UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

LINDSAY PIERCE and THE PEOPLE OF CALIFORNIA and THE STATE OF ILLINOIS *ex rel.* LINDSAY PIERCE, Plaintiffs, vs. OTSUKA HOLDINGS CO., LTD.; OTSUKA AMERICA, INC., and AVANIR PHARMACEUTICALS, INC., Defendants.	No. 1:18-cv-2268 **Judge James Gwin** **Magistrate Judge David A. Ruiz** **Jury Trial Demanded** **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

FIRST AMENDED COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT, THE CALIFORNIA INSURANCE FRAUD PREVENTION ACT, AND THE ILLINOIS INSURANCE CLAIMS FRAUD PREVENTION ACT

TABLE OF CONTENTS

This action is brought by LINDSAY PIERCE ("Relator"), pursuant to the False Claims Act ("FCA"), 31 U.S.C. § 3730(h), and on behalf of the People of California and the State of Illinois, pursuant to the California Insurance Fraud Prevention Act ("CIFPA"), Cal. Ins. Code § 1871.7, and the Illinois Insurance Claims Fraud Prevention Act ("IICFPA"), 740 Ill. Comp. Stat. 92/1 *et seq.*, respectively, by and through her attorneys, against DEFENDANTS OTSUKA HOLDINGS CO., LTD.; OTSUKA AMERICA, INC. ("Otsuka"), and AVANIR PHARMACEUTICALS, INC. ("Avanir" or, collectively, "Defendants").

I. SUMMARY

1. Relator brings this action on behalf of the People of California and the State of Illinois to recover damages and civil penalties under CIFPA and IICFPA against Defendants for causing the submission of false or fraudulent claims; for making, using, or causing to be made or used false records or statements material to false or fraudulent claims; and for conspiring to do all of the same. Relator further brings this action pursuant to the anti-retaliation provision of the federal FCA, 31 U.S.C. § 3730(h), to recover damages against Defendants for retaliating against Relator for her whistleblowing activity.

2. Until it was acquired by San Francisco-based Otsuka in December 2014 for $3.54 billion, Los Angeles-based Avanir had been a small, single-product pharmaceutical company that had designs on making a blockbuster out of its only marketed drug even though it had a very limited indication: pseudobulbar affect ("PBA"), frequent episodes of "sudden uncontrollable and inappropriate laughing or crying."[1] Avanir's lone product was Nuedexta (dextromethorphan hydrobromide and quinidine sulfate).

[1] Mayo Clinic Staff, *Pseudobulbar Affect*, Mayo Clinic (May 16, 2018), https://www.mayoclinic.org/Diseases-Conditions/Pseudobulbar-Affect/Symptoms-Causes/Syc-20353737.

3. Even though its drug had a limited treatable on-label population,[2] Avanir hatched a multi-pronged and fraudulent scheme to grow sales in California, Illinois, and elsewhere illegally: (a) induce select Key Opinion Leader ("KOL") physicians to prescribe Nuedexta off-label by paying enormous kickbacks; (b) market Nuedexta well beyond its FDA-approved indications, despite having no substantial evidence supporting such claims; (c) target its sales force at long-term care ("LTC") patients suffering from vague symptoms they would claim were associated with PBA; and (d) pay its sales force virtually unlimited bonuses, which had the intended effect of rewarding the reckless and wanton promotion of the drug.

4. Commencing in October 2010 and continuing into the present, Avanir has defrauded Medicare, Medicaid, and other federal and state funded health care programs ("Government Programs") and California and Illinois commercial payors and managed care organizations ("MCOs") by providing astronomical financial rewards to specialist physicians such as neurologists, psychiatrists and internal medicine physicians ("KOLs"), especially those practicing out of nursing homes or other LTC facilities, thereby inducing them to prescribe Nuedexta off-label.

5. As part of its scheme, since shortly after Nuedexta's FDA approval in 2010, Avanir has systematically bribed California and Illinois KOLs with hundreds of thousands of dollars per year in fee-for-service payments where the "services" (*i.e.*, consulting and speaking services) were often not provided at all or where the "service" amounted to little more than Avanir-paid social occasions or vacations.

---

[2] In 2007, it was estimated that just 880,000 people in the United States suffered from PBA. S. Clairborne Johnston & Stephen L. Hauser, *Marketing and Drug Costs: Who is Laughing and Crying?*, 61 Annals of Neurology 11A, 11A (2007).

6. For example, it became common practice to pay resident physicians at nursing homes to "speak" to their own staff about Nuedexta. This scheme proved to be highly effective at creating a sense of indebtedness to Avanir, while simultaneously encouraging the physician's staff to interpret such speeches (if they even occurred at all) to constitute directives to identify and place as many patients as possible on Nuedexta. These payments by Avanir consisted of barely-disguised kickbacks in exchange for prescribing Nuedexta, including in off-label circumstances.

7. In only a three-year span from 2013 to 2016 (for which speaker program payment data is available), Avanir paid more than $13 million in speaker fees, of which over $5 million was paid to approximately 50 physician KOLs, nearly all of whom were top prescribers of Nuedexta for LTC patients. A disproportionate number of these prescribers are based in California and Illinois. For example, of the $13 million paid out in total, $1 million was directed to just two high-prescribing physicians in California: Dr. Jason Kellogg of Irvine, California (paid $513,624 by Avanir from 2014-2016); and Dr. Romeo Isidro of Northridge, California (paid $475,447 by Avanir from 2014-2016). Similarly, Dr. Shyam Puppala of Chicago, Illinois, and with whom Relator interacted personally, was paid $197,880.31 by Avanir from 2014-2016. These speaker fees were meant to induce or reward the prescribing of Nuedexta.

8. The scheme has been enormously successful. Avanir's highest paid KOL speakers have prescribed Nuedexta at extremely high levels as a direct result of the inducements Avanir paid to influence prescribing behavior.

9. The scheme has been (and continues to be) conducted on a massive scale, particularly considering the small PBA on-label patient population. For example, Dr. Kellogg of Irvine, California submitted the 16th-most most Medicare Part D claims for reimbursement in

2016 in the entire United States, out of a total of nearly 10,000 U.S. prescribers. As set forth above, Dr. Kellogg has been rewarded handsomely for his behavior. Dr. Kellogg and other KOLs engage in inappropriate Nuedexta prescribing with regard to commercial payors in California, as well.

10. Kickbacks paid to physicians are illegal under Cal. Ins. Code § 1871.7 and 740 Ill. Comp. Stat. 92/5. By 2008, enhanced federal enforcement and revised industry guidelines had curtailed much of these tactics in most of the industry, but Avanir continued these practices, carefully honing its ability to distribute large amounts of money to KOLs while concealing its illegal kickback activity.

11. Avanir's fraudulent activity extends beyond the payment of illegal kickbacks. Since Nuedexta's approval in October 2010, Avanir and its KOLs have promoted Nuedexta off-label, and continue to do so, despite having no adequate clinical evidence supporting these claims, thereby causing the submission of extraordinary numbers of false and fraudulent claims for reimbursement by California and Illinois commercial payors.

12. For example, Avanir has targeted, and continues to target, Alzheimer's and dementia patients, even though Nuedexta's label clearly states that "NUEDEXTA has not been shown to be safe or effective in other types of emotional lability that can commonly occur, for example, in Alzheimer's disease or other dementias."

13. Avanir has also violated federal laws and regulations by knowingly misrepresenting the number of people suffering not just from PBA, but from the symptoms of PBA, to cause prescribers to associate PBA with a vague set of symptoms rather than an actual disease state. These strategies created what Avanir knew were false diagnoses and resulted in the prescribing of Nuedexta to thousands of patients without a PBA diagnosis at all.

14. In perhaps its most blatantly illegal promotion, Avanir has promoted Nuedexta for use in individuals suffering from drug-use related hypoxia, despite a total dearth of clinical evidence supporting Nuedexta's effectiveness for such treatment.

15. In express violation of law and FDA regulations, and with no adequate clinical evidence to support such claims, Avanir has even suggested to prescribers that such vague symptoms (or symptoms associated with Alzheimer's or dementia) could constitute PBA.

16. Likewise, Avanir has created an entire sales force devoted to calling on nursing homes and LTC facilities, knowing that the recruitment of a select few KOLs at such facilities primed with kickbacks would yield a rich vein of new Nuedexta patients. Avanir targeted these LTC patients, knowing that they were more likely to display symptoms that an understaffed LTC facility would willingly treat with Nuedexta. That a willing KOL had been the recipient of the Company's largesse made Avanir's targeting of these vulnerable patients that much easier.

17. The final ingredient in Avanir's fraudulent scheme was its unique unlimited incentive compensation packages, which rewarded sales representatives with huge bonuses for selling Nuedexta for conditions for which the FDA had not approved the drug and for which there was little, if any, supporting clinical evidence of Nuedexta's effectiveness.

18. Avanir's fraudulent scheme has had a material effect on California and Illinois commercial payors' decisions to pay for Nuedexta prescriptions. Had the California or Illinois payors reimbursing for Nuedexta known that claims for the drug were submitted as the result of Avanir's fraud, they would not have made those reimbursements.

19. The People of California and the State of Illinois have suffered substantial harm because of Avanir's false and misleading promotion and payment of kickbacks. California

commercial payors reimburse approximately 12% of the nation's share of drug claims, while Illinois payors reimburse approximately 4% of the nation's share of drug claims.

20. Avanir has violated the federal FCA, CIFPA and IICFPA, and in so doing, has deceived the federal Government and California commercial payors into paying hundreds of millions of dollars in Nuedexta claims that were not eligible for reimbursement.

21. The aforementioned conduct is ongoing.

22. Avanir also retaliated against Relator for her whistleblowing activity. After witnessing a blatant instance of off-label promotion by her immediate supervisor, Relator corrected the false statement and confronted her supervisor. The following day, she was fired. As a result of Avanir's retaliation, Relator has suffered, and continues to suffer, severe financial and psychological harm.

II. JURISDICTION AND VENUE

23. According to 28 U.S.C. §§ 1331 & 1345, this District Court has original jurisdiction over the subject matter of this civil action since it arises under the laws of the United States—in particular, the FCA. In addition, the FCA specifically confers jurisdiction upon the United States District Court. 31 U.S.C. § 3732(b).

24. Pursuant to 28 U.S.C. § 1367, this District Court has supplemental jurisdiction over the subject matter of the claims brought pursuant to CIFPA and IICFPA because the claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

25. This District Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because Defendants transact business in this district and engaged in

wrongdoing in this district. Likewise, the FCA authorizes nationwide service of process and the Defendants have sufficient minimum contacts with the United States of America.

26. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b). Defendants have transacted business within this District, and acts proscribed by 31 U.S.C. § 3729 occurred in this District.

27. Relator is unaware of any public disclosure of the information or allegations that are the basis of the Complaint. If there has been a public disclosure, Relator is the original source of the information and allegations contained in this Complaint. Prior to the filing of this action, Relator voluntarily provided the California Insurance Commissioner and Sacramento County District Attorney with substantially all material evidence and information in Relator's possession regarding the false claims that are the subject of this Complaint.

28. The causes of action alleged herein are timely brought because of, among other things, efforts by the Defendants to conceal from the United States, the People of California, and the State of Illinois their wrongdoing in connection with the allegations made herein.

III. PARTIES

A. Plaintiff/Relator Lindsay Pierce

29. Plaintiff/Relator Lindsay Pierce ("Relator") is a resident of Illinois. Relator received a Bachelor of Science in Business Merchandising from Florida State University.

30. Relator has spent nearly her entire professional career in pharmaceutical sales and has received numerous awards. She began her career in pharmaceutical sales with Eli Lilly, where she excelled for nearly seven (7) years. Relator won President's Club[3] three (3) of those

[3] President's Club is the highest honor for sales representatives at most pharmaceutical companies, awarded annually. The winners of President's Club typically earn bonuses and sometimes are invited to go on lavish trips. In addition, these winners are often singled out for

years and was in the top third of sales representatives in a fourth year. After leaving Eli Lilly, Relator spent three (3) years at Endo Pharmaceuticals, where she won President's Club one year, was a quarterly contest winner for 2 quarters in another year, and ranked in the top 15% in yet another year.

31. Relator was hired by Avanir on or about April 4, 2018, as a Senior Neuroscience Area Manager, LTC in the South Chicago, Illinois territory. Neuroscience Area Managers are known internally as National Account Managers ("NAMs"), and NAMs assigned exclusively to Avanir's LTC sales force are known as LNAMs. Accordingly, Relator was a Senior LNAM. Relator was assigned to report to Chris Grenfell, who was a Regional Business Director ("RBD").

32. Relator's base compensation package at Avanir was $130,000 annually along with the ability to earn significant bonuses based upon sales performance metrics discussed in more detail below.

33. Relator is an original source of the allegations in this Complaint, and her allegations are not based upon publicly disclosed information. She voluntarily provided the California Insurance Commissioner and the Sacramento County District Attorney with substantially all material evidence and information in Relator's possession regarding the false claims alleged herein prior to the filing of her original Complaint, in accordance with Cal. Ins. Code § 1871.7(e)(2). Prior to filing her original Complaint, Relator brought the wrongdoing described therein to the attention of Avanir. After filing her amended Complaint, Relator voluntarily provided the Cook County and Sangamon County State's Attorneys, as well as the

---

praise at the company's annual sales meeting. The awarding of President's Club is based on both objective sales data and subjective factors, including leadership skills and positive cultural fit within the company.

Illinois Attorney General, with substantially all material evidence and information in Relator's possession regarding the false claims alleged herein.

B. Defendants Otsuka and Avanir

34. Defendant Avanir Pharmaceuticals, Inc. is a corporation organized under the laws of Delaware and with a principal place of business at 30 Enterprise, Suite 400, Aliso Viejo, CA 92656.

35. Defendant Otsuka America, Inc. ("Otsuka America") is a corporation organized under the laws of Delaware and with a principal place of business at One Embarcadero Center, Suite 2020, San Francisco, CA 94111.

36. Defendant Otsuka Holdings Co., Ltd. ("Otsuka Japan") is the parent company of Otsuka America and is a foreign company based in Tokyo, Japan. Defendant Otsuka Japan purchased Avanir in December 2014 for $3.54 billion.

37. Defendants market and sell brand-name prescription drug products (including Nuedexta) that are paid for or reimbursed by California and Illinois commercial payors and various governmental programs, including health benefit carriers offering benefits under the Federal Employees Health Benefits ("FEHB") program under a prime contract with the Blue Cross Blue Association; the Health Insurance Program for the Elderly and Disabled, more commonly referred to as the Medicare Program; and various other programs (collectively, the "Government Programs").

38. Avanir's fraudulent schemes also targeted and defrauded private health insurance companies and other health benefits providers in California and Illinois, including, without limitation, health benefit plans, health maintenance organizations, purchasing alliances, carriers, employers, pharmacy benefit managers, third party administrators, and MCOs, on a massive

scale. Avanir's fraudulent practices caused doctors to write prescriptions for Nuedexta that they otherwise would not have written, and caused MCOs to pay reimbursement claims for prescriptions of Nuedexta that they otherwise would not have paid.

39. Because of Defendants' actions, the United States, the People of California, and the State of Illinois have suffered financial harm.

40. Although Avanir has a code of conduct, the code of conduct does not mention the importance of employees' compliance with fraud, waste, and abuse laws enacted to prevent fraud, overutilization, and over-billing, and which safeguard the health and safety of Government Program beneficiaries. *See generally* Avanir Code of Conduct (2018), *available at* http://www.avanir.com/sites/default/files/doc031001.pdf.

IV. NATURE OF ACTION

A. The California Insurance Frauds Prevention Act (CIFPA)

41. The California Legislature enacted CIFPA to combat abusive practices aimed at defrauding private insurance providers. The legislature stated that it was specifically concerned with fraud on health insurance providers: "Health insurance fraud is a particular problem for health insurance policyholders. Although there are no precise figures, it is believed that fraudulent activities account for billions of dollars annually in added health care costs nationally. Health care fraud causes losses in premium dollars and increases health care costs unnecessarily." Cal. Ins. Code § 1871(h).

42. CIFPA subjects any person who violates Cal. Ins. Code § 1871.7(a), or Sections 549, 550, or 551 of the California Penal Code, to civil penalties of between $5,000 and $10,000, plus an assessment of not more than three times the amount of each claim for compensations, as defined pursuant to a contract of insurance. Cal. Ins. Code § 1871.7(b). CIFPA also vests the

court with "the power to grant other equitable relief, including temporary injunctive relief, as is necessary to prevent the transfer, concealment, or dissipation of illegal proceeds, or to protect the public." *Id.*

43. Cal. Ins. Code § 1871.7(a) prohibits the knowing employment of "runners, cappers, steerers or other persons to procure clients or patients ... to perform or obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer."

44. Pursuant to California Penal Code § 549, it is unlawful for any firm or corporations to "solicit[], accept[], or refer[] any business to or from any individual or entity with the knowledge that, or with reckless disregard for whether" that individual intends to make or cause to be made any false or fraudulent claim for payment of a health care benefit.

45. Pursuant to California Penal Code § 550(a)(5), it is unlawful to "[k]nowingly prepare, make, or subscribe any writing, with the intent to present or use, or to allow it to be presented, in support of any false or fraudulent claim," or to aid, abet, solicit, or conspire with any person to do the same.

46. Pursuant to California Penal Code § 550(a)(6), it is unlawful to "[k]nowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit," or to aid, abet, solicit, or conspire with any person to do the same.

47. Pursuant to California Penal Code § 550(b)(1), it is unlawful to "[p]resent or cause to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact," or to knowingly assist or conspire with any person to do the same.

48. Pursuant to California Penal Code § 550(b)(2), it is unlawful to "[p]repare or make any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact," or to knowingly assist or conspire with any person to do the same.

49. In addition, California Business & Professional Code § 650(a) provides that "the offer, delivery, receipt, or acceptance by any person licensed under this division ... of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest, or co-ownership in or with any person to whom these patients, clients, or customers are referred, is unlawful."

50. Section 650 does not require that a violation be committed knowingly or willfully. "The violation of section 650 is a general intent crime, requiring proof only that the defendant offered consideration as inducement for referrals; no specific intent is required." *People v. Guiamelon*, 205 Cal. App. 4th 383, 399-400, 140 Cal. Rptr. 3d 584, 595 (Cal. Ct. App. 2012) (citing *People v. Hering*, 976 P.2d 210 (Cal. 1999). "Section 650 was enacted (1) to ensure that referrals would not be induced by considerations other than the best interest of the patient and (2) to prevent patients being charged more for treatment because of an additional hidden fee imposed to recoup payment for securing the referral." *Id.* at 400, 140 Cal. Rptr. 3d at 595 (citations and internal quotation marks omitted).

51. Through its fraudulent scheme, Avanir violated the preceding provisions, making or causing fraudulent health care claims to be made to California commercial payors. By doing

so, Avanir substantially increased California commercial payors' costs and increased the costs of their participants' coverage.

B. The Illinois Insurance Claims Fraud Prevention Act ("IICFPA")

52. The Illinois Legislature enacted the Illinois Insurance Claims Fraud Prevention Act (IICFPA) to combat abusive practices aimed at defrauding private insurance providers. The legislative findings and declarations make clear that it was specifically concerned with the social costs of fraud on private insurance providers, noting that the penalties in the IICFPA are "remedial" and intended to achieve the "goals of disgorging unlawful profit, restitution, compensating the State for the costs of investigations and prosecution, and alleviating the social costs of increased insurance rates due to fraud." 740 Ill. Comp. Stat. 92/5(c).

53. IICFPA subjects any person who violates any provision thereof or certain criminal code sections (Section 17-8.5 ["Fraud on a governmental entity"] or Section 17-10.5 ["Insurance fraud"] of the Criminal Code of 1961 or the Criminal Code of 2012, or Article 46 ["Insurance Fraud, Fraud on the Government, and Related Offenses"] of the Criminal Code of 1961), each addressed sequentially below, to civil penalties of between $5,000 and $10,000, plus an assessment of not more than three times the amount of each claim for compensations under a contract of insurance. 740 Ill. Comp. Stat. 92/5(b). IICFPA also vests the court with "the power to grant other equitable relief, including temporary injunctive relief, as is necessary to prevent the transfer, concealment, or dissipation of illegal proceeds, or to protect the public." *Id.*

54. 740 Ill. Comp. Stat. 92/5(a) makes it "unlawful to knowingly offer or pay any remuneration directly or indirectly, in cash or in kind, to induce any person to procure clients or patients to obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured person or the person's insurer."

55. Section 17-8.10.5(a)(1) of the Illinois Criminal Code of 2012 states that a "person commits insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property." 720 Ill. Comp. Stat. 5/17-10.5(a)(1).

56. Section 17-8.10.5(a)(2) of the Illinois Criminal Code of 2012 sets forth that a "person commits health care benefits fraud against a provider, other than a governmental unit or agency, when he or she knowingly obtains or attempts to obtain, by deception, health care benefits and that obtaining or attempt to obtain health care benefits does not involve control over property of the provider." 720 Ill. Comp. Stat. 5/17-10.5(a)(2).

57. Section 17-8.10.5(b)(1) of the Illinois Criminal Code of 2012 defines "aggravated insurance fraud" as 3 or more offenses within an 18-month period arising out of separate incidents or transactions. 720 Ill. Comp. Stat. 5/17-10.5(b)(1).

58. Section 17-8.10.5(b)(2) of the Illinois Criminal Code of 2012 further prohibits being an "organizer" of an aggravated insurance fraud, setting forth that a "person commits being an organizer of an aggravated insurance fraud on a private entity conspiracy if aggravated insurance fraud on a private entity forms the basis for a charge of conspiracy under Section 8-2 of this Code and the person occupies a position of organizer, supervisor, financer, or other position of management within the conspiracy." 720 Ill. Comp. Stat. 5/17-10.5(b)(2).

59. Section 17-8.10.5(c) of the Illinois Criminal Code of 2012 sets forth that:

> If aggravated insurance fraud on a private entity forms the basis for charges of conspiracy under Section 8-2 of this Code, the person or

> persons with whom the accused is alleged to have agreed to commit the 3 or more violations of this Section need not be the same person or persons for each violation, as long as the accused was part of the common scheme or plan to engage in each of the 3 or more alleged violations.

720 Ill. Comp. Stat. 5/17-10.5(c).

60. Article 46 of the Illinois Criminal Code of 1961 set forth that a "person commits the offense of insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company or by the making of a false claim to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property." 720 Ill. Comp. Stat. 5/46-1(a) (effective January 1, 2006 through June 30, 2011).

61. Article 46 of the Illinois Criminal Code of 1961 further prohibited aggravated fraud, setting forth that a "person commits the offense of aggravated fraud when he or she, within an `8 month period, obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or insurance companies, a self-insured entity or self-insured entities, or any governmental entity or governmental entities by the making of 3 or more false claims or by causing 3 or more false claims to be made arising out of separate incidents or transactions in violation of Section 46-1 or 46-1.1 of this Code." 720 Ill. Comp. Stat. 5/46-2 (effective January 1, 2006 through June 30, 2011).

62. Article 46 of the Illinois Criminal Code of 1961 further prohibited conspiracy to commit fraud, setting forth:

> A person commits conspiracy to commit fraud when, with the intent that a violation of Section 46-1, 46-1.1, or 46-2 of this Code be committed, he agrees with another to violate Section 46-1, 46-

> 1.1, or 46-2. No person may be convicted of conspiracy to commit fraud unless an overt act or acts in furtherance of the agreement is alleged and proved to have been committed by him or by a co-conspirator and the accused is a part of a common scheme or plan to engage in the unlawful activity. Where the offense agreed to be committed is a violation of Section 46-2, the person or persons with whom the accused is alleged to have agreed to commit the 3 or more violations of Section 46-1 or 46-1.1 need not be the same person or persons for each violation, as long as the accused was a part of the common scheme or plan to engage in each of the 3 or more alleged violations.

720 Ill. Comp. Stat. 5/46-3 (effective January 1, 2006 through June 30, 2011).

63. Article 46 of the Illinois Criminal Code of 1961 further prohibited being an "organizer" of an aggravated fraud conspiracy, setting forth:

> A person Commits the offense of being an organizer of an aggravated fraud conspiracy when he: (1) with the intent that a violation of Section 46-2 of this Code be committed, agrees with another to the commission of that offense; and (2) with respect to other persons within the conspiracy, occupies a position of organizer, supervisor, financer, or other position of management.
>
> No person may be convicted of the offense of being an organizer of an aggravated fraud conspiracy unless an overt act or acts in furtherance of the agreement is alleged and proved to have been committed by him or by a con-conspirator and the accused is part of a common scheme or plan to engage in the unlawful activity. For the purposes of this Section, the person or persons with whom the accused is alleged to have agreed to commit the 3 or more violations of Section 46-1 or 46-1.1 of this Code need not be the same person of persons for each violation, as long as the accused occupied a position of organizer, supervisor, financer, or other position of management in each of the 3 or more alleged violations.

720 Ill. Comp. Stat. 5/46-4 (effective January 1, 2006 through June 30, 2011).

64. Through its various schemes, described *infra*, Avanir violated the preceding provisions, making or causing fraudulent health care claims to be made to Illinois commercial payors. By doing so, Avanir substantially increased Illinois commercial payors' costs and in turn increased the costs of their participants' coverage.

C. The False Claims Act

65. The FCA, 31 U.S.C § 3729(a)(1)(A), prohibits, *inter alia*: knowingly presenting or causing to be presented to the United States any false or fraudulent claim for payment or approval; knowingly making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim; and conspiring to commit a violation of the FCA. If a party violates the FCA, the United States may recover three times the amount of the damages the Government sustains plus a civil monetary penalty of between eleven thousand one hundred eighty-one dollars ($11,181) and twenty-two thousand three hundred sixty-three dollars ($22,363) per claim.

66. The FCA defines a "claim" to include any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient. Any claim submitted by a Medicare or a Medicaid provider for a payment constitutes a claim under the FCA. Any claim submitted by a provider for payment by a federal insurance plan, such as Tricare, is also a "claim" for purposes of the FCA.

67. The FCA further states: "Any employee ... shall be entitled to all relief necessary to make that employee ... whole, if that employee ... is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee ... in furtherance of an action under [the FCA] or other efforts to stop 1 or more violations of [the FCA]." 31 U.S.C. § 3730(h)(1). If an employer violates this provision, the employee is entitled to "reinstatement with the same seniority status that employee ... would have had but for the discrimination, 2 times the amount

of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees." *Id.* § 3730(h)(2).

D. Drug Approvals and Off-Label Promotion

68. Under the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-397, new drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

69. The FDCA and FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81. The drug labeling regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by the FDA. Moreover, this regime protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on misleading marketing tactics.

70. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355(b)(1)(A).

71. The FDA approves a drug if there are "adequate and well-controlled clinical trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use. *See* 21 U.S.C. § 355(d)(5).

72. After a drug is approved, the FDA continues to exercise control over the product labeling. To ensure or promote safety, the FDA may require a label change to reflect the

increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. *See* 21 C.F.R. § 201.57(3).

73. The FDA determines the requirements for package inserts or prescribing information that is provided with a prescription medication, which provide information about that drug.

74. Drug labels—including all marketing and promotional materials relating to the drug—may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. Illegal "misbranding" can result in criminal penalties. *See* 21 U.S.C. § 333. Drug companies can rely only on "substantial clinical evidence" in promoting their drugs. Under 21 CFR 202.1(e)(4)(ii)(c), "substantial clinical evidence" is "... experience adequately documented in medical literature or by other data ... on the basis of which it can fairly and responsibly be concluded by qualified experts that the drug is safe and effective for such uses." Generally, "substantial evidence" requires support from at least two adequate and well-controlled studies, each convincing on its own to establish effectiveness.[4] Moreover, FDA regulations prohibit off-label advertising, 21 C.F.R. § 202.1(e)(6)(i) & 21 C.F.R. § 202.1(e)(4)(i)(a), and off-label promotion by way of oral or written statements, see 21 C.F.R. § 201.5(a).

75. The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. Promotional materials may make claims only that are supported by "substantial" scientific evidence (according to strict scientific procedures) and that are not false or misleading. The risks as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the

[4] Food & Drug Admin., *Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* 3 (May 1998), *available at* https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072008.pdf.

FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved, as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

76. A manufacturer wishing to market or otherwise promote an approved drug for uses other than those listed on the approved label must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* 21 C.F.R. § 314.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301 *et seq.* The manufacturer must also file a supplemental NDA. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

77. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified on the label, or treating a different patient population, *e.g.*, treating a child when the drug is approved only to treat adults.

78. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA.

79. When considering off-label prescribing, physicians depend on the patient-specific evidence available to them. This includes the particular patient, the severity of his or her problems, the successfulness of prior treatment, and the risks of not treating. Whether contemplating on- or off-label use, physicians also rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trials

evidence. Physicians rely largely on information (or misinformation) provided by sales personnel from drug makers, drug company sponsored continuing medical education ("CME") courses and speaker programs, and drug company sponsored clinical trials.

80. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group that is unapproved. Specifically, a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. In addition, the FDCA, 21 U.S.C. § 331(d), and its implementing regulations, prohibit any advertising that recommends or suggests an off-label use for an approved drug.

81. The FDA has interpreted "advertising" to include any "information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product." *See* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64074, 64076 (Dec. 3, 1997). Thus, drug labeling requirements apply to any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer, or distributor of the drug. *See* 21 U.S.C. § 352(f) (requiring labeling to include "adequate directions for use"); 21 C.F.R. § 201.5(a) (stating that "oral, written, printed or graphic advertising" that suggests off-label use constitutes inadequate directions for use); 21 C.F.R. 202.1(e)(4)(i)(a) ("An advertisement for a prescription drug ... shall not recommend or suggest any use that is not in the labeling accepted in such approved new drug application or supplement ...."); 21 C.F.R. 202.1(e)(6)(xi) (prohibiting the use of "literature, quotations, or

references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling").

82. Any drug manufacturer speech explaining one of its products is also subject to the FDA's "fair balance" requirements, which prohibit, among other things, advertisements that "contain[] a representation or suggestion that a drug is better, more effective, useful in a broader range of conditions or patients ..., safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience," 21 C.F.R. § 202.1(e)(6)(i), as well as advertisements that "contain[] a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated," 21 C.F.R. § 202.1(e)(6)(iv).

83. FDA regulations further require drug companies to present a "true statement" of information relating to the side effects, contraindications and effectiveness of the drug use. *See* 21 C.F.R. §§ 202.1(e)(5) *et seq.* A company violates this regulation if it presents "false or misleading" information about a drug's side effects or does not "fair[ly] balance" information relating to the safety and efficacy of the drug use against information about its side effects and contraindications. 21 C.F.R. § 202.1(e)(5)(i)-(ii).

84. Moreover, FDA regulations require labeling to be "informative and accurate and neither promotional in tone nor false and misleading in any particular" and to "contain a summary of the essential scientific information needed for the safe and effective use of the drug," 21 C.F.R. § 201.56(a)(1)-(2), and they prohibit "implied claims or suggestions of drug use

if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness." *Id.* § 201.56(a)(3).

85. A manufacturer may disseminate written information regarding unapproved or new uses of marketed drugs only under certain circumstances. This material must be in the form of an unabridged reprint or copy of a published, peer-reviewed article—or an unabridged reference publication that includes information about a clinical investigation—that is considered "scientifically sound" by experts qualified to evaluate the safety or effectiveness of the drug involved. *See* 21 C.F.R. § 99.101(a)(2). The FDA does not consider abstracts of publications to be "scientifically sound." 21 C.F.R. 99.101(b)(1)(ii). Unabridged reprints or copies of articles may not be disseminated with any information that is promotional in nature. *Id.* § 99.101(b)(2).

86. The violation of any of the aforementioned requirements or prohibitions renders a drug "misbranded" and no longer eligible for reimbursement by Government Programs, including Medicaid.

E. Prescription Drug Payment under Commercial Insurance in California and Illinois

87. Avanir's schemes targeted and defrauded private health insurance companies and other health benefits providers in California and Illinois, including, without limitation, health benefit plans, health maintenance organizations, purchasing alliances, carriers, employers, pharmacy benefit managers, third party administrators, and MCOs, on a massive scale. Avanir's fraudulent practices caused doctors to write prescriptions for Nuedexta that they otherwise would not have written, and caused commercial payors to pay reimbursement claims for prescriptions of Nuedexta that they otherwise would not have paid.

88. Rather than work with commercial payors to gain coverage for Nuedexta, Avanir chose instead to deceive them. Avanir's primary tactic has been to deploy its sales force to essentially bribe doctors to prescribe Nuedexta.

89. Because of the fraudulent and deceptive conduct described in this Complaint, California and Illinois commercial payors have incurred millions of dollars in extra costs, thereby injuring the millions of beneficiaries, employers and other health benefit sponsors which seek to control prescription drug costs.

1. *Avanir Kickbacks Defraud California and Illinois Commercial Payors*

90. California and Illinois commercial payors aim to provide appropriate, affordable and accessible services and products to achieve positive short-term and long-term patient outcomes.

91. California and Illinois commercial payors routinely use a variety of tools and strategies, frequently in tandem, to achieve the goals of making available services and goods appropriate for the varied needs of beneficiaries, while managing costs for both beneficiaries and plan sponsors.

92. Pharmaceuticals play an important role in the prevention, cure, and management of disease. At the same time, expenditures for drugs have been increasing at rates higher than or comparable to expenditures for other health-related products and services, and are expected to continue to increase.

93. A primary focus of California and Illinois commercial payors is to lower their expenditures on pharmaceuticals. In doing so, they save money for both plan sponsors and patients who pay the premiums, and ultimately help ensure the affordability and sustainability of drug benefit coverage.

94. Avanir's fraudulent schemes were intended to and did interfere with California and Illinois commercial payors' cost control programs by inducing health care professionals to prescribe, and/or to fill prescriptions with Avanir when doing so was not medical necessary or inappropriate.

95. Avanir's kickback schemes were intended to, and did, cause doctors to prescribe Avanir's more expensive branded prescriptions of Nuedexta in violation of California and Illinois commercial payors' cost-containment policies.

2. *Competitive Choice as a Cost-Containment Strategy*

96. A fundamental aspect of California and Illinois commercial payors' cost-containment strategies is to ensure the availability of competitive services and products, grounded in the economic principle that free-market competition will keep prices down.

97. Avanir's practices deprived California and Illinois commercial payors and their beneficiaries of the pricing and selection benefits of free-market competition.

98. Avanir's practices also deprived California and Illinois commercial payors and their beneficiaries of the independent judgment of various health care professionals. Instead, the commercial payors' beneficiaries were steered or compelled to use Nuedexta—regardless of whether Nuedexta was the best and/or most economical product for the beneficiaries' needs.

3. *California Commercial Payors' Provider Agreements and Manuals*

99. California commercial payors also attempt to control costs through the terms of their "provider" or "participating physician" agreements. These agreements are the contracts that commercial payors require physicians to sign before the payors will cover the physicians' services.

100. Provider agreements universally require the provider to certify that he or she will provide covered patients with medical services that are "medically necessary." Insurers typically consider goods and services to be "medically necessary" only if they are not costlier than an alternative service or sequence of services that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patients' illness, injury, or disease.

101. Provider agreements also require providers to certify that they will provide services in accordance with applicable federal and state laws and regulations. Provider agreements universally require providers to certify that they will comply with California Business & Professional Code § 650(a), which provides that "the offer, delivery, receipt, or acceptance by any person licensed under this division ... of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest, or co-ownership in or with any person to whom these patients, clients, or customers are referred is unlawful."

102. Several California commercial payors also have programs under their provider agreements in which doctors are offered financial incentives for meeting certain performance goals in furtherance of cost-containment objectives. Avanir's kickback schemes were intended to, and did, circumvent the cost-control measures California commercial payors sought to achieve through their provider agreements. Avanir caused doctors to write prescriptions that did not comply with the certifications the doctors made in their provider agreements. Additionally, Avanir provided financial inducements to doctors to prescribe Nuedexta that offset the financial incentives commercial payors provide for doctors to prescribe more cost-effective generic drugs.

4. *Illinois Managed Care Organizations and Cost-Containment Strategies*

103. The goal of MCO health care coverage in Illinois is to provide appropriate, affordable and accessible services and products in order to achieve positive short-term and long-term patient outcomes.

104. Illinois MCOs routinely use a variety of tools and strategies, frequently in tandem, to achieve the goals of making available services and goods appropriate for the varied needs of beneficiaries, while managing costs for both beneficiaries and plan sponsors.

105. As alleged in this Complaint, Avanir's fraudulent schemes were intended to and did interfere with Illinois MCOs' cost control programs by inducing health care professionals to prescribe, recommend and/or fill prescriptions with Avanir when doing so was not medically necessary or inappropriate.

106. Pharmaceuticals play an important role in the prevention, cure, and management of disease. At the same time, expenditures for drugs have been and are expected to continue to increase at rates higher than or comparable to expenditures for other health-related products and services.

107. A primary focus of Illinois MCOs is to lower their expenditures on pharmaceuticals. In doing so, they save money for both plan sponsors and patients who pay the premiums, and ultimately help ensure the affordability and sustainability of drug benefit coverage.

108. The goal of Illinois MCOs' prescription drug benefit programs is to provide appropriate, affordable and accessible coverage so that positive patient outcomes are achieved. Managed care drug benefit coverage programs routinely use a variety of tools and strategies, frequently in tandem, to achieve the goal of managing costs for consumers and plan sponsors.

109. As alleged in this First Amended Complaint, Avanir's fraudulent schemes were intended to and did interfere with Illinois MCOs' cost control programs by inducing health care professionals to prescribe, and/or to fill prescriptions with Nuedexta when doing was not medically necessary or inappropriate.

5. *Illinois MCOs' Use of Formularies*

110. In providing coverage for prescription medicines, Illinois private insurers implement managed care cost-containment programs that promote lower-cost drug equivalents to expensive brand-name drugs. Such programs involve restrictions on reimbursement of expensive brand name drugs through the use of "formularies."

111. Most commercial MCOs have preferred drug lists known as "formularies," which designate drugs covered by the plan. Formularies are critical mechanisms for controlling prescription drug program costs because they incentivize patients to make efficient and economical choices when medically suitable alternatives exist. If a drug is "on formulary," it will be covered when prescribed (potentially subject to restrictions to ensure that it is being properly prescribed).

112. Decisions about which drugs to include on a formulary are typically made by a committee of experts referred to as pharmacy and therapeutics (P&T) committees. Made up of physicians, pharmacists, and other clinical experts, these committees review clinical evidence for all drugs in a given therapeutic class. The formulary may exclude some drugs in a class, for example, older drugs that have been replaced in practice with safer, more effective alternatives. A formulary generally includes at least one drug in each therapeutic category. Where multiple drugs in a class are considered generally equivalent, the committee may narrow the list of alternatives based on clinical or cost factors.

113. Formularies are a tool MCOs use for price negotiation. A formulary is a list of drugs an Illinois MCO has approved for reimbursement. To get a particular drug approved and placed on an MCO's formulary, a drug manufacturer typically must agree to pay the MCO a rebate that reduces the MCO's cost of covering the drug.

114. By placing a drug on its formulary, the Illinois MCO may also have increased leverage with manufacturers. By creating the ability to steer utilization toward a particular drug, the plan can offer higher volume in exchange for a lower price or a higher rebate from the manufacturer. A tighter formulary or stronger incentives will increase this leverage.

115. As alleged in this First Amended Complaint, Avanir's kickback schemes were intended to and did interfere with Illinois MCOs' formulary cost control programs by inducing physicians to prescribe Nuedexta in non-medically necessary or inappropriate circumstances.

6. Higher Co-Payments for Non-Formulary, Non-Preferred Medications

116. A co-payment is a fixed charge that patients must pay for each prescription they fill. In general, Illinois MCOs impose higher patient co-payments for using non-formulary, non-preferred medications in an effort to get patients to consider more carefully whether a non-formulary medication is necessary. Higher co-payment cost sharing for non-formulary, non-preferred drugs generates substantial savings for Illinois MCOs.

117. MCOs utilize a "tiered" formulary system, in which the level of co-pay required from and reimbursement provided to the insured patient depends on the formulary tier in which the drug is placed. And a drug's placement in an MCO's formulary tier will depend largely on its cost to the MCO.

118. In a typical Illinois MCO formulary, "Tier One" is comprised of generic drugs—*i.e.*, drugs that are no longer covered by patent protection and thus may be produced and/or

distributed by multiple drug companies at a lower price relative to their branded counterparts. Generic drugs thus play a critical role in MCOs' attempts to curb ever-escalating prescription drug costs. On average, generics cost MCOs $16 per script, while preferred brands cost $118 per script and non-preferred brands cost $124 per script. Tiered cost-sharing provisions thus incentivize generics by imposing a lower co-pay or co-insurance for generics than for brands in Tiers Two or Three.

119. Tier Two is comprised of "preferred" drugs. They are drugs included on a formulary or other preferred drug list; for example, a brand name drug without a generic or brand substitute.

120. Tier Three is comprised of "non-preferred" drugs. They are drugs not included on a formulary or preferred drug list; for example, a brand name drug that has a generic substitute.

121. Illinois MCOs thus encourage their beneficiaries to choose Tier One drugs by imposing a lesser co-pay than that imposed for Tier Two or Three drugs. Tiered co-payments and co-insurance (which is a percentage of the overall cost of the drug at retail rather than a flat dollar figure) thereby provide reasonable personal financial incentives to individuals to use equally effective, but less costly, medications.

122. Managed care cost savings are thus achieved by the differential co-payments between Tier 1, Tier 2, and Tier 3, which incentivize patients and their prescribers to use the lowest cost formulary Tier.

123. As alleged in this First Amended Complaint, Avanir's kickback schemes were intended to and did interfere with Illinois MCOs' use of these cost control measures.

7. *Prior Authorization Requirements*

124. In most instances, drugs that are not on formulary are not covered by the plan, and patients must pay the full cost themselves. However, Illinois MCOs will make an exception and cover a non-formulary drug if the drug is medically necessary for a particular patient—*i.e.*, if there is a reason why the on-formulary medication is not an acceptable alternative. In such cases, the prescribing physician requests a "prior authorization" (also known as an "exception request" or "coverage determination request") for the patient to receive coverage for the non-formulary drug.

125. Under a prior authorization, the health plan or pharmacy benefit manager must authorize a particular prescription before it can be filled. A legitimate clinical reason must exist for the Illinois MCO to grant the prior authorization request. Common reasons include contraindications of the formulary medication to other medications that the patient is already taking, or a prior adverse experience of the patient to the formulary-listed medication.

126. Prior authorization is used as a means of enforcing the formulary or preferred drug list. Drugs that are not on the formulary or preferred list might be available only through a prior authorization, in contrast to a tiered approach that incentivizes patient behavior through different levels of co-payments.

127. One MCO's prior authorization form demonstrates how prior authorizations enforce formulary restrictions and incentives. First, the form requires the physician to indicate the medication requested, as well as the reason for the prior authorization request. The form then requires the doctor to "Provide Details Regarding All Formulary Alternatives Tried." It notes that "Failure of <u>All</u> Formulary Alternatives Is Required for Approval." The doctor must then list each formulary alternative, the dose and frequency used, and "Describe Specific and Significant

Side Effects and/or Ineffectiveness" of the formulary drug. The doctor then must sign the request form.

128. The representations made in a prior authorization form thus are, by their very nature, material to an MCO's decision to provide coverage for a prescription claim. Indeed, that is the sole point of a prior authorization: to get the insurer to reimburse a claim that it otherwise would not.

129. The prior authorization process is used by the vast majority of MCOs in Illinois to enforce their formulary restrictions and thus control the cost of pharmaceuticals, while permitting the substitution of non-formulary drugs when medically necessary for particular patients.

130. As alleged in this First Amended Complaint, Avanir's schemes were intended to and did interfere with Illinois MCOs' use of the prior authorization mechanism by, among other things, falsifying prior authorization requests to steer patients to the use of its drugs.

8. *Provider Agreements and Manuals*

131. Illinois MCOs also attempt to control costs through the terms of their "provider" or "participating physician" agreements, as set forth in the Provider Application/Agreement and in the Provider Manual. Collectively, those documents are the contracts MCOs require physicians to sign and be bound by before the MCO will cover the services or goods.

132. For example, provider agreements universally require the provider to certify that he or she will provide covered patients with medical services that are "Medically Necessary." A common definition among insurers is that a good or service is "Medically Necessary" only if it is "not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patients'

illness, injury, or disease." *See, e.g.*, *BlueCross BlueShield of Illinois Provider Manual, Billing and Reimbursement* 4 (Oct. 2018), *available at* https://www.bcbsil.com/pdf/standards/manual/billing_and_reimbursement.pdf. Insurers also typically mandate that "[s]ervices should be provided in the most cost effective manner and in the least costly setting required for the appropriate treatment of the member." *Id.*

133. Providers are also required to provide services in accordance with the law. For example, BlueCross BlueShield of Illinois states that benefit coverage is subject to "applicable state and/or federal law." *Id.* at 6.

134. The insurers also have the right to enforce these requirements through audits of the provider's billing and other practices affecting the integrity of the claims submitted to the insurer for payment. *See, e.g.*, *id.* at 4. Indeed, insurers typically create special investigations departments which "identif[y] and investigate[] conduct that may constitute health care fraud or abusive billing." *See, e.g.*, *BlueCross BlueShield of Illinois Provider Manual, Fraud and Abuse Program* 2 (Oct. 2018), *available at* http://www.bcbsil.com/pdf/standards/manual/fraud_and_abuse.pdf.

135. By making such representations and warranties to MCOs, healthcare providers certify, among other things, that they will comply with the Illinois Insurance Claims Fraud Prevention Act.

136. As alleged in this Second Amended Complaint, Avanir's kickback schemes were intended to, and did, circumvent the cost-control measures Illinois MCOs sought to achieve through their provider agreements. In particular, Avanir's payments of kickbacks to health care providers caused those health care providers to write and/or fill prescriptions for Nuedexta that did not comply with the certifications made in the provider agreements and undermined the

financial inducements offered by the MCOs to the health care providers designed to further cost-containment objectives.

9. *Participating Pharmacy Network Contracting*

137. Network contracting is another basic service provided by Illinois MCOs. Specifically, the MCO contracts with a group of pharmacies, negotiating discounted drug prices and fees on behalf of the plan sponsor. Sometimes, the MCO will negotiate preferred network arrangements, in which members pay lower cost-sharing amounts at certain pharmacies. An MCO may also have a limited network, meaning a network from which at least one major pharmacy chain has been eliminated. Usually, the preferred or mandated pharmacies have agreed to give the MCO discounts on drugs and services in exchange for increased volume at their stores.

138. These MCO network pharmacy arrangements save money, both for the plan sponsors who pay for the majority of the drug benefit, and for the enrollees who often pay a portion of the plan premiums (monthly fees for health care coverage) and out-of-pocket costs.

139. MCO participating pharmacy network contracts typically require the collection of the applicable enrollee co-payment, coinsurance, or deductible at the time of dispensing.

140. MCO network pharmacy agreements also contain cost-containment terms requiring the network pharmacy to follow the terms of the formulary, including prior authorization, generic substitution, and collection of co-payments.

141. As alleged in this First Amended Complaint, Avanir's kickback schemes were intended to and did interfere with Illinois MCOs' use of pharmacy networks, in violation of cost-containment provisions in participating pharmacy agreements.

V. BACKGROUND ALLEGATIONS

A. Pseudobulbar Affect ("PBA")

142. PBA is a neurological condition that affects a person's outward expression of emotion.

143. As a neurologic condition itself, PBA is most often associated with a prior underlying neurological injury, such as multiple sclerosis ("MS"), amyotrophic lateral sclerosis ("ALS"), or Parkinson's Disease.

144. The primary symptoms of PBA are frequent and involuntary outbursts of crying or laughing that are not connected to the person's emotional state. Crying is more commonly observed than laughing. A person's mood will appear normal between episodes.

145. PBA is a relatively rare condition. According to a 2007 American Neurological Association ("ANA") article, it was estimated that about 880,000 people in the United States suffered from PBA.[5]

146. Avanir has sought to inflate the prevalence estimates to convince physicians that PBA is much more common than it is, and, consequently, to increase sales of Nuedexta—the only FDA-approved treatment for PBA. For example, PBAinfo.org is a non-branded website created by Avanir to "educate" patients about the disease state. The following screen capture of the website suggests that over 7 million people might suffer from PBA:[6]

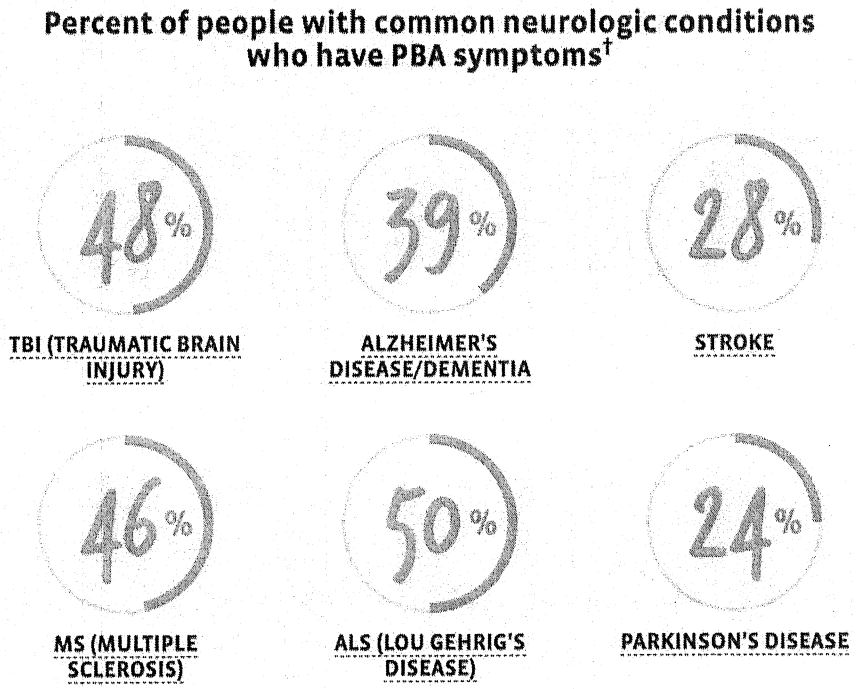
PBA is more common than you think.

While there are almost **2 million people** in the US with neurologic conditions or traumatic brain injury who have PBA, over **7 million people** in the US have symptoms that may suggest PBA*:

[5] Johnston & Hauser, *supra* note 2, at 11A.

[6] *About PBA*, PBA Info, https://www.pbainfo.org/about-pba (last visited Feb. 22, 2019).

147. This nearly eight-fold increase in PBA prevalence is presented without citation and relies in part on associating PBA with more prevalent conditions, despite a complete lack of evidence supporting these claims. Just below this statement on Avanir's non-branded PBA website is a graphic suggesting a very high prevalence of PBA in individuals suffering from Alzheimer's Disease/dementia, MS, ALS, Parkinson's Disease, stroke, and traumatic brain injury ("TBI"):



148. While Avanir's website cites a single study to support these prevalence associations, its website does not disclose that the primary author of the study is an Avanir employee named Susan Work, or that the study was based upon patient surveys designed to result in affirmative answers to PBA symptoms.

149. In an April 2011 slide deck created by Avanir, a slide titled "PBA Prevalence" suggested that "18 to 20 million people in U.S. [have] underlying neurologic conditions" suggestive of PBA and that up to 20% of those individuals had PBA and that were "many more with mild PBA." The citations for these statistics were to "Avanir data on file."

150. Geriatric medicine experts generally believe that only about five percent, not thirty-nine percent, of dementia patients have PBA (and likely because they also have an underlying neurological condition such as MS, ALS, or Parkinson's Disease).

151. The same slide deck stated that Avanir's primary "Commercialization Strategy" was to "[i]ncrease diagnosis and treatment of PBA." Avanir did so through rampant off-label promotion.

152. In fact, the very first slide of Relator's first training module created by Avanir for sales training asserted that PBA is associated with conditions that are not supported by independent scientific evidence:

> 1.1 Introduction
>
> Pseudobulbar affect (PBA) is a disorder of emotional expression characterized by involuntary, sudden, and frequent episodes of laughing and/or crying that typically occur out of proportion or incongruent to the underlying emotional state. PBA occurs secondary to other neurological conditions: dementias, including Alzheimer's disease (AD), stroke, traumatic brain injury (TBI), multiple sclerosis (MS), Parkinson's disease (PD), and amyotrophic lateral sclerosis (ALS).

153. By reinforcing these off-label disease associations based on inherently unreliable patient self-assessment surveys, Avanir trained its sales force to promote Nuedexta for off-label use among Alzheimer's and dementia patients, as well as for stroke or TBI patients, using what it knew was false and misleading evidence.

B. Nuedexta: The Only FDA-Approved PBA Treatment

154. While Nuedexta is the first and only FDA-approved PBA treatment available in the United States, both of the active pharmaceutical ingredients in Nuedexta are off-patent. Dextromethorphan is the active ingredient in many over-the-counter cough suppressants and has been widely available to U.S. consumers since at least 1958. Quinidine sulfate is available as a generic medication and has been used as an anti-arrythmatic agent since at least the early twentieth century. Purchased separately, these two products would cost only about $20 per month.

155. Nuedexta, a combination of these two inexpensive ingredients, is nonetheless quite expensive. In 2011, at the time of launch, Avanir priced Nuedexta at about $5,000 per year.[7] Avanir has since increased the price some 200% since 2011. Nuedexta now costs almost $15,000 annually.

156. Nuedexta is approved by the FDA only for the treatment of PBA.

157. Upon the launch of Nuedexta, Avanir had grand visions for additional follow-on indications, including behavioral symptoms associated with dementia. To date, however, the FDA has approved no additional indications. The leading and most commonly available approved compendium, Drugdex, does not support the off-label use of Nuedexta for any condition. Nevertheless, Avanir has continued to promote Nuedexta off-label, including for behavioral symptoms associated with dementia.

158. Avanir has reaped enormous profits from the drug, notwithstanding the fact that Nuedexta is a derivative medication into which Avanir invested relatively modest research and

[7] Katherine Hobson, *Lawmakers Aren't Laughing About Avanir's Price for Nuedexta*, Wall St. J. (May 25, 2011, 5:16 pm), https://blogs.wsj.com/health/2011/05/25/lawmakers-arent-laughing-about-avanirs-price-for-nuedexta/.

development. In fact, President and CEO Keith Katkin stated Avanir's R&D minimal philosophy on a Fourth Quarter 2010 Earnings Call: "[M]any biotech companies start as research and development companies ... whereas we here at Avanir, the entire management team has grown up, essentially, on the commercial side of the business."

159. Revenues for Nuedexta have skyrocketed since launch, and, consequently, so have claims for reimbursement from California commercial payors. Nuedexta sales rose from $37 million in 2012 to $218 million in 2016.

160. In 2014, trusting the profitability of Nuedexta, Avanir's only FDA-approved product, Defendant Otsuka purchased Avanir for $3.539 billion. Defendant Otsuka is thus under considerable pressure to earn a profit from Nuedexta.

VI. AVANIR'S FRAUDULENT MARKETING SCHEME

161. It was against the foregoing backdrop that Avanir developed and deployed a fraudulent scheme characterized by false and misleading statements at every turn, to induce physicians to prescribe Nuedexta, and thereby cause false claims for reimbursement to be submitted to (and paid by) commercial insurance companies including in California and Illinois.

162. Avanir's aggressive effort to put Nuedexta in America's medicine cabinet was so brazen that Avanir successfully turned a condition affecting less than 0.3% of the U.S. population into a blockbuster drug widely used in nursing homes.

A. Avanir-Sponsored Disease Prevalence Studies Falsely Associate PBA with Non-Neurological Conditions and Suggest a Misleading Sevenfold Increase in PBA Prevalence

163. Prior to Nuedexta's development and approval, no person or entity had an incentive to inflate the disease prevalence estimates for the relatively rare condition known as PBA.

164. As Avanir began to develop Nuedexta, it sought to alter the PBA prevalence discourse by polluting the medical literature with studies which it had funded and designed, and which were ghostwritten by Avanir employees.

165. Indeed, in a 2011 Avanir slide deck, the company noted that its principal marketing goal was to "[i]ncrease diagnosis and treatment of PBA." Avanir sought to accomplish this goal through two prevalence studies that appear throughout Avanir's non-branded marketing materials, including those presented by Avanir's California- and Illinois-based sales force to California and Illinois physicians.

1. *The PRISM Study*

166. Chief among these studies is the so-called PBA Registry Series ("PRISM") Study, funded and designed by Avanir, which was intended to yield results suggesting a much higher PBA prevalence among patients with certain other neurological conditions.

167. PRISM's authors included four doctors on Avanir's payroll and one Avanir employee, Randall Kaye. The study was conducted by enlisting investigators at several sites to hand-pick twenty or more consenting patients with any of the following conditions: Alzheimer's Disease, ALS, MS, Parkinson's Disease, stroke, or TBI. There was no randomization procedure for enrollment in PRISM, which likely resulted in bias related to investigators seeking out patients with likely PBA symptoms.

168. The PRISM study administered a seven-item questionnaire ("CNS-LS") originally developed in 1997 to study PBA symptoms in ALS patients ("the Moore Study"[8]), with four questions for laughter and three for crying. Those seven items included score options of 1

[8] Stan R. Moore *et al.*, *A Self-Report Measure of Affective Lability*, 63 J. Neurology, Neurosurgery, & Psychiatry 89, 89-93 (1997).

(Never), 2 (Rarely), 3 (Occasionally), 4 (Frequently), or 5 (Most of the Time). In the Moore study, the authors applied factor loading of less than one (between 0.55 and 0.83) to each answer such that different answers produced different weights on the scale. With factor loading, a score of 13 or greater was determined to result in the identification of affective lability and possible PBA using CNS-LS.

169. The PRISM Study authors departed from the Moore Study method in a significant way. The PRISM study authors did not use factor analysis; instead, they tabulated the total scores assigning a value of 1 to each answer, but kept the score of 13 or greater as the threshold for the presence of PBA symptoms. This resulted in an inflated rate of PBA diagnosis using the CNS-LS questionnaire. As an example of how easy it was to be diagnosed with PBA under such a method, if a patient answered "Rarely" to every question, the PRISM Study authors would conclude that such a person had the "presence of PBA symptoms." This deliberately flawed patient enrollment procedure and methodology resulted in the study authors finding that nearly 37% of the patients enrolled in PRISM had the presence of PBA symptoms.

170. Avanir used the flawed PRISM study results to suggest that more than seven million people in the United States suffered from PBA, a 795% leap from the 880,000 estimated in 2007. This analysis still appears on Avanir's PBAinfo.org website.

171. Avanir does not discloses on the PBAinfo.org website that the PRISM study patient enrollment procedures were deeply flawed; that its use of the CNS-LS questionnaire departed from the original designers' use of the questionnaire; that the study had been designed by Avanir; that the PRISM authors were on Avanir's payroll; or that the manuscript that discussed these results was ghostwritten by Avanir employees.

172. The PRISM Study was a centerpiece of Avanir sales representative training. In Module 2 of its training materials, the PRISM study is discussed and taught to sales representatives to be used as part of the promotion of Nuedexta. Neither Relator nor any of Relator's co-trainees were ever told of the study's inherent flaws, nor of Avanir's control over the publication of its results.

2. *The Work Online Survey*

173. In another study created by, staffed by, and authored by Avanir employees, the study authors conducted an online survey using the same CNS-LS questionnaire (and same flawed scoring method) as well as what it calls the "Pathological Laughing and Crying Scale" (or "PLACS") tool. The primary author is an Avanir employee named Susan Work. Ms. Work's qualifications to conduct a proper scientific survey are dubious. She holds a Bachelor of Arts in English Literature from Bryn Mawr College, and is the Senior Director of Commercial Analytics at Avanir. The study itself was designed by Avanir and the accompanying article ghostwritten by Avanir employees.

174. Of the 38,000 individuals invited to participate, only 2,318 completed the questionnaire. And of those who participated, mean prevalence was only 10.1% using PLACS, and only 9.4% using the CNS-LS tool with a "more rigorous" score threshold of 21 or greater. Again, using the unjustifiably low CNS-LS score threshold of 13 or greater resulted in a 37.5% PBA prevalence rate among the six studied conditions (only three of which are related to PBA). The authors used these unreliable results to conclude that PBA was "under-recognized."

175. In justifying Avanir's contention that PBA prevalence rates are significantly "under-recognized" and that seven million or more people have PBA, Avanir cites primarily to the Work study and to the PRISM study in its non-branded promotional materials, including

those presented by Avanir's California- and Illinois- based sales force to California and Illinois physicians.

B. Avanir's Off-Label Promotion of Nuedexta

176. Presenting highly suspect evidence concerning the size of the on-label market was just one aspect of Avanir's multi-faceted effort to increase Nuedexta prescribing and consequently Avanir's own profits.

177. Having suggested to prescribers that PBA was significantly under-diagnosed through Avanir's pollution of the medical literature, Avanir next targeted unstudied populations sought to associate vague symptoms with PBA, knowing that these symptoms are not likely to actually be associated with PBA, and encouraged its sales force to promote Nuedexta for conditions for which Avanir knew there was no evidentiary support for Nuedexta's safety or efficacy.

1. *Avanir promotes Nuedexta for Alzheimer's disease/dementia and for geriatric use generally.*

178. Nuedexta's label states that "[t]he pharmacokinetics of [Nuedexta] have not been investigated systematically in elderly subjects (aged >65 years) ...." Indeed, only 14% of clinical trial patients were 65 and older, and only two percent 2% were 75 and older. The Nuedexta clinical trials thus did not include enough geriatric patients to determine whether such patients would respond differently than younger patients.

179. According to the Family Caregiver Alliance, approximately 63% of LTC patients are 65 or older.[9]

[9] *Selected Long-Term Care Statistics Caring for Adults with Cognitive and Memory Impairment*, Family Caregiver Alliance (Jan. 31, 2015), https://www.caregiver.org/selected-long-term-care-statistics.

180. In addition, Nuedexta's label states that "NUEDEXTA has not been shown to be safe or effective in other types of emotional lability that can commonly occur, for example, in Alzheimer's disease or other dementias." Despite these limitations, Avanir saw nursing home and LTC patients as such a potential cash cow for Nuedexta sales that it created a dedicated LTC sales force, of which Relator was a part.

181. For example, Relator was presented with a "target list" of LTC and nursing homes (and affiliated prescribers) in the Chicago-South District to which she was assigned in Illinois. Upon researching these facilities, Relator found that few, if any, of these targets included PBA patients, and that these facilities treated few patients with relevant associated neurological conditions. Relator's counterparts in California received similar such "target lists."

182. For example, one of Relator's assigned LTC targets was Oak Lawn Respiratory & Rehab, 9525 South Mayfield, Oak Lawn, IL 60453. Oak Lawn has 143 beds, according to data furnished to Relator by Avanir, but at the time Relator examined relevant data, there were no patients with PBA or with any underlying neurological condition associated with PBA at Oak Lawn. Avanir intended for Relator to target this facility for off-label promotion of Nuedexta for geriatric use or Alzheimer's/dementia.

183. Relator encountered a similar circumstance at the Alden Estates of Orland Park, located at 16450 South 97th Avenue, Orland Park, Illinois. The Alden Estates has 200 beds, according to data furnished to Relator by Avanir, but at the time Relator examined relevant data, there were no patients with PBA or any underlying neurological conditions associated with PBA at the Alden Estates. Avanir intended Relator to target this Illinois facility for off-label promotion of Nuedexta for geriatric use or Alzheimer's/dementia.

184. The trend continued throughout the dozens of LTC/nursing homes Avanir asked Relator to target. There were approximately 9,707 beds in LTC targets in Relator's Chicago-South District. At the time Relator conducted research into patient profiles of these facilities, only 306 (or ~3.1%) had underlying diagnoses of neurological conditions associated with PBA.

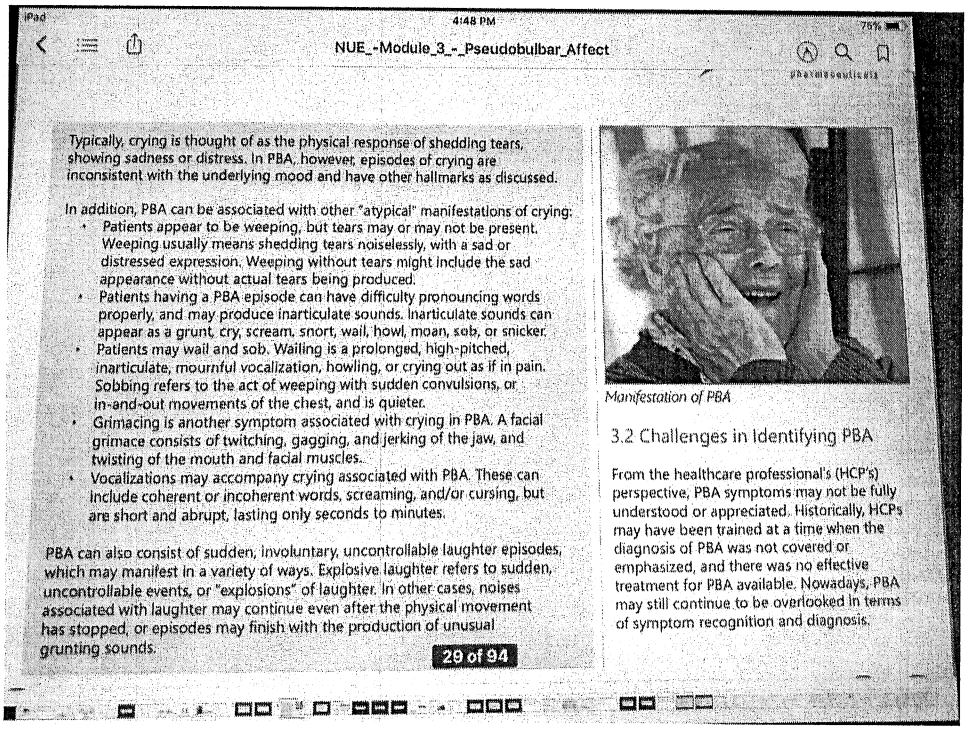
185. Avanir was simply marketing Nuedexta for Alzheimer's/dementia and for geriatric use generally, including in California and Illinois.

2. *Avanir promotes Nuedexta off label for "inarticulate sounds," "sad expressions," and "random" expressions of emotion.*

186. One of the principal reasons Avanir targeted LTC care institutions was the fact that symptoms associated with general cognitive decline caused by aging or by Alzheimer's/dementia could be readily confused with PBA.

187. Avanir included symptoms in its promotional materials that are not symptoms of PBA to cause providers to prescribe Nuedexta to geriatric patients without PBA.

188. For example, Relator captured the following image of a slide that appeared in Module 3 of her training materials. The slide displays a picture of an elderly woman. The slide states that PBA symptoms may manifest as "inarticulate sounds" that may "appear as a grunt, cry, scream, snort, wail, howl, moan, sob, or snicker." These vague symptoms are common among elderly patients in cognitive decline and any connection between these symptoms and PBA is highly attenuated.



189. Avanir explicitly encouraged its sales representatives to promote Nuedexta for off-label uses in unstudied aging populations, or among populations where Nuedexta had been studied but had failed to demonstrate safety or efficacy (Alzheimer's/dementia).

190. The slide also states that "[a] facial grimace" such as "twitching, gagging, and jerking of the jaw, and twisting of the mouth and facial muscles" could be associated with PBA. As with "inarticulate sounds," Avanir knew that such gestures are more likely not associated with PBA.

191. Relator and other LTC sales representatives were instructed to describe these symptoms to prescribers as being indicative of PBA when they knew that PBA was unlikely to be the underlying cause.

192. Avanir also promoted the idea that any kind of "random" expression of emotion could be a manifestation of PBA. In fact, Avanir promotes on its website that PBA symptoms may simply include a "sad or distressed expression" or "sad appearance."

193. Although Avanir later determined these descriptions to be misleading and thus removed them from sales training materials, the same misleading language remains on the Nuedexta medical professionals ("HCP") website.[10]

194. Avanir's Nuedexta.com and PBAinfo.org websites are likewise replete with references to the alleged association between PBA and Alzheimer's and dementia even though PBA is not traditionally associated with these conditions and the fact that Nuedexta is not approved for patients suffering from such conditions.

3. *Avanir promotes Nuedexta for drug abuse-related hypoxia.*

195. Certain narcotics (including opiates and opioids) reduce breathing and heart rates. In an overdose situation, the brain may be deprived of oxygen resulting in hypoxia and possible permanent brain damage.

196. Avanir knew that a substantial number of LTC patients had a history of drug abuse.

197. During an in-service presentation about Nuedexta that occurred in Illinois, after Relator had concluded an on-label detail of the drug, Chris Grenfell (Relator's RBD) addressed the attendees, including numerous staff doctors and nurses, and asked whether Lydia Healthcare had any drug abuse patients with hypoxia. Grenfell knew the facility had numerous such patients. Grenfell then announced, falsely, that Nuedexta had been approved for treatment of drug abuse hypoxia.

198. After he had falsely told the attendees that Nuedexta had been FDA-approved for drug abuse-related hypoxia, Grenfell then departed the facility. Relator, who stayed at the

[10] *PBA & Long-Term Care*, NuedextaHCP.com, https://www.nuedextahcp.com/understanding-pba/pba-long-term-care (last visited Feb. 22, 2018).

facility, corrected Grenfell's false statements and explained to the attendees that Nuedexta was not in fact approved for such use.

199. This encounter resulted in retaliation by Avanir in the form of Relator's employment termination the next day, discussed in further detail below.

C. Avanir's Uncapped Bonuses Reward Its Sales Force for Promoting Nuedexta Off-Label

200. Until recently, Avanir had a highly unusual uncapped and lock-in incentive compensation ("IC") program for its sales force, which had the effect of growing Nuedexta sales far beyond the PBA patient population of around 1 million people.

201. As stated by then-President and CEO Keith Katkin during a First Quarter 2011 Earnings Call, "we've set up an uncapped compensation program for our field sales representative .... [I]t is based on prescriptions generated."[11]

202. To incentivize the LTC sales force to generate LTC prescriptions, the IC plan states that "LNAMs/LASRs will only cover the LTC channel," thus preventing other bonus opportunities. The measurement for incentive compensation is the "Nuedexta target pay" multiplied by the "% of target pay" attained as set on a quarterly basis by sales management. There is no limit on the amount of the bonus that a sales representative can earn.

203. Given that Avanir's own documents acknowledge that only about 100,000 PBA patients resided in nursing homes, the IC plan has incentivized the Avanir sales force to engage in aggressive off-label promotion and kickbacks to physicians treating large numbers of potential Nuedexta patients (*i.e.*, in the LTC setting).

---

[11] *AVANIR Pharmaceuticals Discusses F1Q11 Results - Earnings Call Transcript*, Seeking Alpha (Feb. 3, 2011, 1:52 p.m.), https://seekingalpha.com/article/250612-avanir-pharmaceuticals-discusses-f1q11-results-earnings-call-transcript?page=7.

D. Avanir Pays Massive Kickbacks to Doctors in Exchange for Prescribing Nuedexta Off-Label

204. To stretch Nuedexta's sales even further, Avanir decided to enlist the help of certain high-prescribing physicians—in particular, those with targeted off-label patient populations. Between 2014 and 2016, Avanir paid nearly $14 million to physicians in exchange for Nuedexta loyalty. Millions of dollars were paid to California and Illinois physicians.

205. In recent years, as enforcement of the AKS has increased, many pharmaceutical companies have ceased to engage in the most egregious violations. However, many KOLs remain willing to accept kickbacks, and the easiest way to acquire brand loyalty is to buy it. Since it launched Nuedexta in 2010, Avanir has engaged in marketing programs whose primary (if not sole) purpose was to distribute money to high-level prescribers with the expectation that these KOLs would prescribe Nuedexta in return.

206. Avanir's kickback strategy has focused on multiple means of illegal payments to KOLs and patients. Among the tactics utilized by Avanir were: (1) paying LTC and nursing home physicians to present faulty data concerning Nuedexta to their own staff and encouraging their staff to prescribe Nuedexta off-label; (2) paying LTC and nursing home physicians to "speak" to their own staff knowing that such events never occurred; and (3) paying the physician speakers with the intent to induce favorable prescribing behavior.

207. The effect of these annual six-figure payments on physician prescribing has predictably and intentionally induced health care providers to prescribe Nuedexta. Of the approximately $13 million paid to physicians by Avanir from 2014 to 2016, $5 million was paid to just a small number of doctors—all top Nuedexta Medicare prescribers.

208. Dr. Jason Kellogg, the Medical Director of Hotel California by the Sea, was Medicare's 16th-highest Nuedexta prescriber in 2016. Dr. Kellogg is a prolific prescriber of

Nuedexta, generally causing significant reimbursements by California commercial payors. Hotel California by the Sea specializes in addiction treatment, suggesting that Dr. Kellogg is prescribing Nuedexta inappropriately treating drug abuse-related hypoxia patients. Dr. Kellogg is also the Chief of Staff at the Newport Bay Psychiatric Hospital, which describes itself as a "34 bed, locked, inpatient psychiatric hospital."[12] In 2016, Dr. Kellogg gave sixty-six Avanir-sponsored speaker programs in which he promoted Nuedexta, including during two Avanir-funded trips to Hawaii. Between 2014 and 2017, Dr. Kellogg received $624,968.16 from Avanir and Otsuka. These payments were made to induce Dr. Kellogg to write (or to reward his having written) Nuedexta prescriptions off-label for drug abuse-related hypoxia, dementia, and other non-PBA psychiatric conditions such as agitation, and to induce him to encourage other physicians to do the same. These payments induced Dr. Kellogg to prescribe Nuedexta off-label; many of these prescriptions, were submitted as claims for reimbursement to California commercial payors, who, in turn, paid the claims.

209. Dr. Romeo Isidro is a psychiatrist in Northridge, California, a northern suburb of Los Angeles. Dr. Isidro was in the top 1% of Nuedexta prescribers in 2016. He also was rewarded handsomely by Avanir. Between 2014 and 2017, Avanir and Otsuka paid Dr. Isidro was paid $542,677.63. In 2016 alone, he spoke at sixty-nine Avanir-sponsored programs in which he promoted Nuedexta. Avanir paid Dr. Smirnoff these speaker fees as an inducement to prescribe Nuedexta off-label, or as a reward for having prescribed Nuedexta off-label with the expectation that he would continue to do so. These payments induced Dr. Isidro to prescribe

[12] *Newport Bay Hospital*, Newport Bay Hospital, http://www.newportbayhospital.com (last visited Sept. 18, 2018).

Nuedexta off-label; many of these prescriptions, were submitted as claims for reimbursement to California commercial payors, who, in turn, paid the claims.

210. Dr. Kellogg and Dr. Isidro are outliers because they are psychiatrists. Internal Avanir "target" data shows that of the 98 "10 decile" physician targets (*i.e.*, the highest prescribing doctors) in California, only 14 were psychiatrists—the specialty most likely to appropriately treat with Nuedexta. The remainder were mostly internal or family medicine physicians who were very unlikely to encounter patients with PBA.

211. It is no coincidence that Dr. Kellogg and Dr. Isidro are based in the Los Angeles area. Relator attended a sales force training session with Vincent Ocampo, a Los Angeles-based LTC sales representative who was hired to replace two Los Angeles-based sales representatives who had recently left the company under clouds of suspicion. According to what Relator learned during the training, Kevin Tiffany, the Los Angeles-area regional manager during this period, was pressuring sales representatives to focus their efforts on marketing Nuedexta for use among dementia and Alzheimer's patients. The representatives willingly complied because of the uncapped bonus structure at Avanir. These representatives apparently made so much money that they simply left the company.

E. Avanir Pays Health Care Providers to Promote Nuedexta to Their Staffs

212. In a twist on the typical promotional speaker event, many health care providers were paid by Avanir to deliver lectures to their own staffs. During these paid speaking events, the speakers used an Avanir-created slide deck which presented Avanir's faulty prevalence data suggesting that PBA was far underdiagnosed and suggested prescribing Nuedexta off-label for certain elderly dementia patients. These promotional speaking events to a physician's own staff blur the lines between a favorable discussion of a product and a directive from a supervisor to

use that product. This is precisely why Avanir paid for such events: to induce LTC physician-speakers to deliver tacit or explicit instructions to their employees to prescribe Nuedexta off-label.

213. Dr. Shyam Puppala of Relator's Chicago, Illinois District was Medicare's seventy-sixth-highest Nuedexta prescriber in 2016. Dr. Puppala specializes in geriatric psychiatry. Dr. Puppala spends most of his time traveling between approximately thirteen area nursing homes where he typically serves as the medical director to these facilities.

214. Dr. Puppala is routinely paid by Avanir to deliver promotional speaker programs to the staff at nursing homes where Dr. Puppala has served as the Medical Director. Dr. Puppala was paid $197,880.31 in speaker's fees by Avanir from 2014 to 2016. In 2016, Avanir paid Dr. Puppala for forty-one speaker events and made thirty-six payments to Dr. Puppala for travel and lodging to speak at places to which he was already traveling for work. Avanir paid Dr. Puppala these speaker fees as an inducement to prescribe Nuedexta off-label, or as a reward for having prescribed Nuedexta off-label with the expectation that he would continue to do so. These payments induced Dr. Puppala to prescribe Nuedexta off-label; many of these prescriptions, were submitted as claims for reimbursement to Illinois commercial payors, who, in turn, paid the claims.

215. Many of Dr. Puppala's LTC patients were prescribed Nuedexta only until Dr. Puppala had left as Medical Director. For example, the Heather Health Care Center is a 173-bed facility located at 15600 South Honore Ave., Harvey, IL 60426. Until recently, Dr. Puppala was the Heather Health Medical Director. At that time, more than thirty patients at Heather Health were prescribed Nuedexta, even though Relator's research indicated that there were only eight

patients with PBA-associated neurological conditions. Following Dr. Puppala's departure as Medical Director at Heather Health Care Center, no patients were prescribed Nuedexta.

216. The practice of paying physicians for "speaker events" to discuss Nuedexta their own staff occurred nationwide, including in California and Illinois. Dr. Isidro, for example, was paid by Avanir to conduct sham speaker events to his own staff. Avanir paid these speaker fees as an inducement to prescribe Nuedexta off-label, or as a reward for having prescribed Nuedexta off-label with the expectation that the recipients of the fees would continue to do so. These payments induced providers to prescribe Nuedexta off-label; many of these prescriptions, were submitted as claims for reimbursement to California and Illinois commercial payors, who, in turn, paid the claims.

F. Defendants' Fraudulent Prior Authorization Scheme Constitutes Insurance Fraud

217. California and Illinois commercial payors' attempts to control inappropriate prescribing of Nuedexta have been thwarted by Avanir's practices of bribing physicians to prescribe Nuedexta off-label and conducting aggressive and misleading sales pitches.

218. For example, Blue Shield of California sent a complaint letter to the FDA complaining of Avanir's conduct. Blue Shield then implemented a prior authorization ("PA") protocol for Nuedexta, hoping to limit its use to appropriate circumstances. Other California commercial payors followed suit.

219. PA, in the context of a health care plan, refers to the process of obtaining prior approval from an insurer regarding the correctness, suitability, and coverage of a service or medication that allows the physician and patient to know in advance about whether a procedure, treatment, or service will be covered under a health care plan. By placing an additional barrier

between prescription and reimbursement, the PA process is intended to ensure that prescriptions are issued appropriately.

220. Avanir was prepared for the implementation of PA protocols and deployed its sales force to undermine the PA measures. Relator and other sales representatives, including those in California and Illinois, were instructed to "flag charts"—a practice where the sales representative reviews a physician's patient files and flags patients who the sales representative believes is a candidate for Nuedexta. This practice is a blatant HIPAA violation and a means for Avanir to increase Nuedexta prescriptions.

221. Once candidate patients were identified, Avanir's sales representatives were then instructed to, and did, supply the physician with ICD-10 codes and provide coaching on how to get the PA approved. Avanir sales representatives, including in California and Illinois, even went as far as filling out the actual paperwork for PA requests.

222. Payors often added PA requirements and other restrictions for patients who were diagnosed with PBA and suffered from certain underlying neurological conditions, such as Alzheimer's, TBI, and Parkinson's Disease. BlueCross BlueShield of Illinois was particularly wary of PBA diagnoses that included these underlying neurological conditions. However, BlueCross BlueShield of Illinois, as well as other payors, generally did not add any PA requirements or restrictions for patients who were diagnosed with PBA and suffered from MS.

223. These PA requirements and other restrictions were particularly frustrating to physicians who received speaker fees from Avanir. Avanir would pay speaker fees only to physicians who wrote a high number of prescriptions for Nuedexta. Payors' PA requirements made such prescribing more difficult, as they resulted in additional work for providers and increased the likelihood that a claim for reimbursement would be denied.

224. Therefore, Avanir's sales representatives, following instructions from Avanir, coached physicians to report a false diagnosis to payors in order to bypass PA requirements. Avanir's sales representatives knew which underlying diagnosis would present fewer restrictions based on the payors in their territory, and they coached providers to falsify diagnoses accordingly. Providers, in turn, reported these false diagnoses to payors when submitting claims for reimbursement, and payors paid those claims.

225. For example, Avanir's sales representatives instructed Dr. Puppala to report to payors that his patients suffered from MS—even though they did not—because payors had not implemented a PA requirement or other restrictions for PBA patients diagnosed with MS. According to the sales representative whose territory included Dr. Puppala's Heather Health Care Center before Relator took over that territory, most of the patients at that facility had been diagnosed with PBA and MS. When Relator asked the sales representative why so many patients shared this diagnosis, he replied that such a diagnosis was a "shoo-in" for insurance approval.

226. Dr. Puppala and other providers followed these and similar instructions and reported false diagnoses to payors in order to bypass PA requirements and other restrictions. Upon receiving claims for reimbursement that reported these false diagnoses, payors paid the claims.

227. By providing false diagnoses to payors, physicians were able to bypass payors' PA requirements and other restrictions and continue to prescribe Nuedexta at high rates. In exchange for their decision to prescribe Nuedexta, Avanir paid or continued to pay sham speaker fees to these physicians.

228. In this manner, California and Illinois commercial payors' PA requirements were undermined and the inappropriate use and reimbursement of Nuedexta continued unabated.

229. Furthermore, Avanir's practice of supplying providers with ICD-10 codes and coaching on how to get PA approval, as well as filling out paperwork for PA requests, constitutes an illegal kickback to physicians. The PA process typically involves the need to provide additional information to the health plan, appeals of rejections, reconsiderations of denials, and other clerical and administrative work, all of which involves a significant expenditure of time by physician office employees, who are paid for their time by the physicians to complete PA and reimbursement work. Providers generally report that this process is burdensome and that follow-up activities are time consuming, leading to staggering administrative costs.

230. By providing free assistance to help providers through the PA process, Avanir provided enormous value to the providers. Had Avanir not provided these services for free, providers would have had to employ and pay their staff to complete these tasks. Instead, as an inducement to prescribe Nuedexta or a reward for having done so, Avanir performed these services, saving providers a significant amount of money and inducing unnecessary and inappropriate prescribing of Nuedexta.

G. California Is the Epicenter of Defendants' Fraudulent Scheme

231. Avanir's fraudulent scheme was executed nationwide, but California—which is the largest pharmaceutical market in the nation—was its epicenter.

232. Both Avanir and Otsuka are based in California, and the fraudulent scheme of causing inappropriate use of Nuedexta emanated, in particular, from Avanir's Aliso Viejo headquarters. All promotional and marketing materials, field directives, coaching strategies, and prior authorization strategies were conceived of and advanced in California.

233. Likewise, several of Avanir's highest-paid speaker KOLs are based in California, including the aforementioned Dr. Jason Kellogg and Dr. Romeo Isidro, who were collectively paid over $1 million by Avanir and Otsuka from 2014-2017.

VII. DEFENDANTS CAUSED THE PRESENTATION OF FALSE CLAIMS TO CALIFORNIA AND ILLINOIS INSURANCE PROVIDERS AND TO THE UNITED STATES

A. Reimbursement for Nuedexta in California and Illinois

234. Avanir provided health care providers with kickbacks for the purpose of illegally inducing and/or rewarding those providers to purchase Nuedexta for use treating beneficiaries of various California and Illinois commercial payors, all in return for or to induce purchasing, ordering, arranging for or recommending purchasing or ordering of goods or items for which payment was made by California commercial payors, in violation of Cal. Ins. Code § 1871.7(b).

235. These kickbacks caused physicians to use Nuedexta rather than cheaper competitor biosimilar drugs.

236. These actions in turn caused health care providers to submit false or fraudulent claims for reimbursement to California and Illinois commercial payors.

237. Claims submitted to California commercial payors where a kickback is involved in the underlying transaction are false within the meaning of the California Insurance Frauds Prevention Act and the Illinois Insurance Claims Fraud Prevention Act.

238. Claims that were submitted to California and Illinois commercial payors as a result, in part or in whole, based on kickbacks provided by Avanir were therefore false within the meaning of the California Insurance Frauds Prevention Act and the Illinois Insurance Claims Fraud Prevention Act.

239. Avanir's payment of kickbacks therefore caused the submission of claims that were false and not eligible for reimbursement to California and Illinois commercial payors.

240. Avanir's payment and offers of payment of kickbacks were made knowingly and with the intent to cause the submission of false claims to California and Illinois commercial payors.

241. California and Illinois commercial payors paid reimbursements for those false claims, and, as a result, have incurred and continue to incur significant damages due to Avanir's illegal payment of kickbacks.

B. Avanir's Kickbacks Induced California and Illinois Health Care Providers to Submit Thousands of False Claims for Reimbursement to California and Illinois Commercial Payors

242. Avanir's scheme was successful and played a substantial role in securing thousands of prescriptions for the drug Nuedexta in exchange for the distribution of payments to physicians. The result has been the improper and illegal submission of claims for reimbursement by California and Illinois commercial payors, and the payment of those claims.

243. California and Illinois doctors wrote increased prescriptions for Nuedexta because of kickbacks, which pharmacies then filled, submitting false claims for reimbursement to federal and state health care programs in violation of federal and state anti-kickback laws. These laws are preconditions for reimbursement. Accordingly, as a result of the kickbacks Avanir offered to physicians, it caused thousands of false claims to be submitted for payment to California and Illinois commercial payors.

244. California and Illinois health care providers violated the anti-kickback laws when they wrote prescriptions for Nuedexta, knowing that claims for reimbursement would be submitted in connection with those prescriptions, in exchange for their offers of kickbacks. These doctors were aware that Avanir's kickbacks were contingent upon increasing the number of prescriptions that the doctors wrote for the drug Nuedexta, and that to continue receiving kickbacks the doctors needed to continue prescribing the drug. Moreover, to participate in the

California and Illinois commercial payor programs that provided reimbursement for those prescriptions, the doctors were required to certify that they were not in violation of state and federal laws, including anti-kickback laws. Accordingly, these doctors knowingly and willfully violated CIFPA and IICFPA when they wrote prescriptions for Nuedexta in exchange for this remuneration, knowing that the prescriptions they wrote would be paid for by these programs.

245. During the period that these doctors were offered kickbacks, these California and Illinois health care providers wrote more prescriptions for Nuedexta than they otherwise would have. These prescriptions later became the subject of claims for reimbursement that were submitted to California and Illinois commercial payors.

246. Avanir knew, and expected, that its kickback scheme would result in reimbursements for their drugs. Nuedexta is reimbursed by California and Illinois insurers under retail and/or mail pharmacy benefit programs, and the Avanir unlawful scheme resulted in misbranded or tainted prescriptions that were presented to these pharmacies. These pharmacies then submitted kickback-tainted false or fraudulent prescription claims to the program responsible for approving and facilitating reimbursement of the false claims.

247. These are, therefore, false records or statements knowingly caused to be made or used by Avanir to get false claims paid and approved by the California and Illinois commercial payors.

248. As such, Avanir has caused false claims to be submitted by California and Illinois physicians and pharmacies.

VIII. AVANIR CAUSED PROVIDERS TO FALSELY CERTIFY COMPLIANCE WITH THE LAW

249. Avanir not only caused pharmacies to submit false claims, it also caused California and Illinois physicians and pharmacies to falsely certify their compliance with

applicable laws which require express and/or implied certifications of compliance with conditions of payment.

250. Avanir also caused California and Illinois physician-providers to falsely certify their compliance in connection with their receipt of kickbacks, including in connection with the Avanir promotion of Nuedexta.

IX. AVANIR UNLAWFULLY RETALIATED AGAINST RELATOR

251. Avanir unlawfully terminated Relator's employment in retaliation for her whistleblowing activities.

252. Given her extensive experience, Relator was hired by Avanir on or about April 4, 2018, as a Senior Neuroscience Area Manager, LTC in the South Chicago, Illinois territory. Neuroscience Area Managers are known internally as NAMs, and NAMs assigned exclusively to Avanir's LTC sales force are known as LNAMs. Accordingly, Relator was a Senior LNAM. Relator was assigned to report to Chris Grenfell, who was an RBD.

253. Even before Relator was hired by Avanir, Avanir's management was extremely impressed by her skill and experience. In fact, Relator was the first LNAM hired by Avanir at the senior level.

254. Relator's salary at Avanir was $130,000 per year, with the ability to earn significant—and uncapped—bonuses based upon sales performance metrics.

255. Immediately after being hired by Avanir, Relator participated in three weeks of training, during which she demonstrated ability and poise far beyond that of her fellow trainees, none of which served at a senior level. For example, during the training sessions, the trainees were occasionally called upon to engage in mock sales exercises. Relator was the only trainee comfortable and skilled enough to effectively complete these exercises as they were intended to

be performed. In addition, when Relator's fellow trainees would ask questions, one of the supervisors conducting the training, Christina Gange, would frequently look to Relator to supply an answer.

256. Relator successfully completed training and was provided with a company car to begin her work as a senior LNAM.

257. On her second day of work post-training, on or about May 31, 2018, Relator was accompanied on a ride-along by her immediate supervisor, Chris Grenfell. The pair visited Lydia Healthcare facility in Robbins, Illinois, a mental health rehabilitation facility with 412 beds. Relator gave a presentation about Nuedexta, in which she described the on-label uses of the drug. Immediately following the presentation, Grenfell complimented Relator on her excellent performance, telling her that she was a "breath of fresh air" and that she would win President's Club. Grenfell's praise indicated that he thought Relator was a good cultural fit for Avanir and had a promising future with the company.

258. Grenfell then addressed the attendees, including numerous staff doctors and nurses, and asked whether Lydia Healthcare had any drug abuse patients with hypoxia. Grenfell knew the facility had numerous such patients. Grenfell then announced, falsely, that Nuedexta had been approved for treatment of drug abuse-related hypoxia.

259. After he had falsely told the attendees that Nuedexta had been FDA-approved for drug abuse-related hypoxia, Grenfell departed the facility.

260. After Grenfell departed the facility, Relator remained behind. Relator was confused, as she did not recall that the FDA had approved an indication for Nuedexta to treat drug abuse-related hypoxia. Relator was concerned that Grenfell had mistakenly—though

fraudulently—promoted off-label use of Nuedexta. Relator consulted her marketing materials and confirmed that Nuedexta was not approved for the treatment of drug abuse-related hypoxia. Relator believed that she was required by the law and by Avanir's Code of Ethics to correct Grenfell's statement. Relator was concerned that Grenfell's statement constituted off-label marketing which could lead to the submission of false claims for reimbursement to insurers, including government health care programs. Accordingly, Relator returned to the room where the presentation had taken place and told the attendees that Nuedexta was not indicated for drug abuse-related hypoxia.

261. Relator then left the facility and telephoned Grenfell. Relator told Grenfell that she had corrected his misstatement because she was concerned that Grenfell had engaged in off-label marketing. Relator asked Grenfell if there was a new indication for Nuedexta that Relator did not know about.

262. Grenfell was angry that Relator had returned and corrected his misstatement to the attendees of the presentation. Grenfell stated, verbatim, to the best of Relator's recollection: "If you could just shut the fuck up, then we won't have a problem and you will win President's Club. Insurance doesn't deny it." By this statement, Grenfell meant that Relator would have a successful career at Avanir if she acquiesced in his fraudulent behavior, because Avanir had marketed Nuedexta for this off-label indication in the past and had been reimbursed by insurers for prescriptions involving that indication. Relator did not say anything in response. The phone call ended shortly thereafter.

263. The following day, Relator was driving to another facility to give another presentation when Grenfell called her. Also on the line was an Avanir Human Resources

representative named Jeanna Mackin. Grenfell did not participate in the conversation. Instead, Mackin told Relator that her employment was being terminated immediately.

264. Mackin told Relator that Relator was a "poor cultural fit" for Avanir and that the decision to terminate Relator had come "from the highest level" in the company. Mackin told Relator that the decision to terminate her was final and there was "no negotiation." Mackin told Relator not to apply for unemployment benefits, stating that Avanir would ensure that such benefits would be denied because Relator was being terminated for cause.

265. The proffered explanation for Relator's termination was pretextual. Relator engaged in protected activity under the FCA—namely, she took action to prevent fraud by investigating whether Grenfell had marketed Nuedexta off-label, correcting Grenfell's fabrication, and confronting Grenfell about the false statement he had made. In so doing, Relator sought to stop potential fraud: the off-label promotion of Nuedexta and the submission of false claims to insurers, including government health care programs, for reimbursement based on that off-label promotion. Avanir knew Relator had engaged in this protected activity once Relator informed Grenfell what she had done. And because Relator engaged in this protected activity, Avanir unlawfully retaliated against her by verbally harassing her during her May 31, 2018 phone call with Grenfell, attempting to induce her not to report any further instances of fraud, terminating her employment, and inducing her not to pursue unemployment benefits. Avanir would not have taken these actions but for Relator's engaging in the protected activity described above.

266. Avanir sought to, and did, intimidate, punish, and retaliate against Relator for her lawful and proper decision to follow company policy and report what she accurately considered

to be illegal directions and activities by her supervisors and Avanir. As such, the company improperly retaliated against Relator because of her whistleblowing activity.

267. As a direct result of Avanir's unlawful retaliation, Relator has suffered, and continues to suffer, severe financial and psychological harm.

268. After being terminated, Relator struggled to find a new job. The circumstances of her departure from Avanir damaged Relator's reputation in the pharmaceutical industry. Relator was unable to provide a positive referral from Avanir or adequately explain the reason she was terminated. As the months wore on, it became more and more difficult for Relator to explain the growing employment gap on her résumé. As a result of these factors, Relator was passed over for multiple job opportunities and lost a significant amount of income. In addition, lest she suffer further retaliation, Relator was afraid to even work in the pharmaceutical industry anymore. To this date, Relator must omit her employment at Avanir from her résumé because her brief period of employment followed by her termination has caused such extensive damage to her professional reputation.

269. Because of the severe psychological and emotional distress Relator suffered after being terminated, Relator sought and received psychiatric treatment, for which she was forced to pay thousands of dollars out of pocket. The psychological harm Avanir caused to Relator is ongoing, and Relator continues to receive psychiatric treatment.

270. To stay financially solvent during her period of unemployment, Relator was forced to deplete her savings and cash in a portion of her 401(k), for which she incurred a significant tax penalty.

271. Relator was discharged, threatened, harassed, and discriminated against by Avanir because of her lawful acts in investigating and reporting compliance violations. As such, Relator

is entitled to reinstatement, two times the amount of her back pay, interest on the back pay, and compensation for all damages allowed by law, including but not limited to special damages, and damages for emotional distress, sustained as a result of her unlawful termination.

X. CAUSES OF ACTION

COUNT I

(Violation of False Claims Act, 31 U.S.C. § 3730(h))

272. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

273. Because of Relator's lawful acts in furtherance of protected activities in the investigation and reporting of fraud, Defendants discriminated against Relator by terminating her employment, inducing her not to apply for unemployment benefits, and refusing to provide a positive reference for prospective employers.

274. Relator's termination of employment was a direct result of Defendants' retaliatory acts, causing Relator to suffer, and continue to suffer, substantial financial and psychological damage in an amount to be proven at trial.

COUNT II

(Violation of California Insurance Frauds Prevention Act)

275. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

276. Defendants knowingly employed physicians as "runners, cappers, steerers, or other persons" by paying them kickbacks to "procure clients or patients to perform or obtain services or benefits under a contract of insurance," in violation of Cal. Ins. Code § 1871.7(a) and Cal. Bus. & Prof. Code § 650(a).

277. Defendants also knowingly employed its sales representatives as "runners, cappers, steerers, or other persons" to cause health care professionals and their staff to be paid kickbacks, and/or to falsify or cause said professionals and staff to falsify health care claims, all to "procure clients or patients to perform or obtain services or benefits under a contract of insurance," and all in violation of Cal. Ins. Code § 1871.7(a) and Cal. Bus. & Prof. Code § 650(a).

278. Through their payment of kickbacks, Defendants knowingly prepared, made, and/or subscribed a writing, with the intent to present or use it, or to allow it to be presented, in support of false and/or fraudulent claims, in violation of Cal. Ins. Code § 1871.7(b) and Cal. Penal Code § 550(a)(5).

279. Through their payment and receipts of kickbacks, Defendants knowingly made or caused to be made false or fraudulent claims for the payment of a health care benefit, in violation of Cal. Ins. Code § 1871.7(b) and Cal. Penal Code § 550(a)(6).

280. Through their payment and/or receipt of kickbacks, Defendants presented or caused to be presented written and/or oral statements as part of, or in support of, claims for payment or other benefit pursuant to an insurance policy, knowing that the statements contained false and/or misleading information concerning one or more material facts, in violation of Cal. Ins. Code § 1871.7(b) and Cal. Penal Code § 550(b)(1).

281. Through their payment and/or receipt of kickbacks, Defendants prepared or made written and/or oral statements that were intended to be represented to an insurer or insurance claimant in connection with, or in support of, claims for payment or other benefits pursuant to an insurance policy, knowing that the statements contained false or misleading information

concerning one or more material facts, in violation of Cal. Ins. Code § 1871.7(b) and Cal. Penal Code § 550(b)(2).

282. The payment and/or receipt of kickbacks as described herein has had the direct effect of significantly increasing the number of claims submitted to and paid by California MCOs for Nuedexta prescriptions, thereby increasing the amount of money spent by California MCOs for this drug.

283. Defendants' payments of kickbacks induced the cooperation of physicians to evade California MCO cost containment programs, and thereby aided and/or abetted Defendants' scheme to induce the dispensing of Nuedexta. This use of kickbacks has had the direct effect of significantly increasing the number of Nuedexta prescriptions, thereby increasing the price of said prescriptions, which were then paid for or reimbursed by California MCOs.

COUNT III

(Violation of Illinois Insurance Claims Fraud Prevention Act)

284. Relator incorporates the preceding paragraphs of this First Amended Complaint as though fully set forth herein.

285. Avanir violated the Illinois Criminal Code and the IICFPA by committing "insurance fraud" through payment of kickbacks and/or falsification of, or causing the falsification of, prior authorization requests and/or health care claims, and/or presenting or causing to be presented written and/or oral statements as part of, or in support of, claims for payment or other benefit pursuant to an insurance policy, knowing that the claims and/or statements contained false and/or misleading information concerning one or more material facts. Avanir knowingly prepared, made, and/or subscribed a writing, with the intent to present or use it, or to allow it to be presented, in support of false and/or fraudulent claims. The foregoing

actions were all in violation of 740 Ill. Comp. Stat. 92/5(a)-(b), the Illinois Criminal Code of 2012 (720 Ill. Comp. Stat. 17-8.10.5(a)(1)), and the Illinois Criminal Code of 1961 (720 Ill. Comp. Stat. 5/46-1(a)) (effective January 1, 2006 through June 30, 2011).

286. Avanir further violated the Illinois Criminal Code and the IICFPA by committing "health care benefits fraud" through payment of kickbacks and/or falsification of, or causing the falsification of, prior authorization requests and/or health care claims, and/or presenting or causing to be presented written and/or oral statements as part of, or in support of, claims for payment or other benefit pursuant to an insurance policy, knowing that the claims and/or statements contained false and/or misleading information concerning one or more material facts. Avanir also knowingly made or caused to be made false or fraudulent claims for the payment of a health care benefit. The foregoing actions were all in violation of 740 Ill. Comp. Stat. 92/5(b) and the Illinois Criminal Code of 2012 (720 Ill. Comp. Stat. 5/17-8.10.5(a)(2)).

287. Avanir's violations of the IICFPA were "aggravated" offenses because Avanir caused 3 or more violations within 18 months, all in violation of 740 Ill. Comp. Stat. § 92/5(b), the Illinois Criminal Code of 2012 (720 Ill. Comp. Stat. 5/17-8.10.5(b)(1)), and the Illinois Criminal Code of 1961 (720 Ill. Comp. Stat. 5/46-2) (effective January 1, 2006 through June 30, 2011).

288. Avanir's violations of the IICFPA were in the nature of a "conspiracy" or "conspiracies" with other persons and/or entities, all in violation of 740 Ill. Comp. Stat. 92/5(b), the Illinois Criminal Code of 2012 (720 Ill. Comp. Stat. 5/17-8.10.5(c)), and the Illinois Criminal Code of 1961 (720 Ill. Comp. Stat. 5/46-3) (effective January 1, 2006 through June 30, 2011).

289. Avanir was the "organizer" of the conspiracy or conspiracies with other persons and/or entities, all in violation of 740 Ill. Comp. Stat. 92/5(b), the Illinois Criminal Code of 2012

(720 Ill. Comp. Stat. 5/17-8.10.5(b)(2)), and the Illinois Criminal Code of 1961 (720 Ill. Comp. Stat. 5/46-4) (effective January 1, 2006 through June 30, 2011).

290. Avanir's payments of kickbacks induced the cooperation of health care providers to evade Illinois MCOs' cost containment programs, and thereby aided and/or abetted Avanir's scheme to induce the dispensing of Nuedexta.

291. The payment and/or receipt of kickbacks as described herein has had the direct effect of greatly increasing the number of claims submitted to and paid by Illinois MCOs and commercial payors for Nuedexta, thereby increasing the amount of money spent by these entities for Nuedexta.

XI. PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against Defendants as follows:

A. That judgment be entered in Relator's favor and against Defendants in the amount of three times the amount of each claim that Defendants presented or caused to be presented to an insurance company, pursuant to Cal. Ins. Code § 1871.7(b);

B. That judgment be entered in Relator's favor and against Defendants in the amount of three times the amount of each claim that Defendants presented or caused to be presented to an insurance company, pursuant to 740 Ill. Comp. Stat. 92/5(b);

C. That judgment be entered in Relator's favor and against Defendants for the relief necessary to make Relator whole as a result of Defendants' unlawful discrimination, including two times the amount of back pay, interest on the back pay, and compensation for special damages sustained as a result of the discrimination, pursuant to 31 U.S.C. § 3730(h)(1)-(2);

D. That judgment be entered in Relator's favor and against Defendants for pre- and post-judgment interest, along with reasonable attorneys' fees, costs, and expenses which were necessarily incurred in bringing and pressing this case, pursuant to Cal. Ins. Code § 1871.7(g)(1)(A)(iii)(I) & 31 U.S.C. § 3730(h)(2);

E. That civil penalties of $10,000 be imposed, pursuant to Cal. Ins. Code § 1871.7(b), for each fraudulent claim that Defendants presented or caused to be presented to a California insurance company;

F. That civil penalties of $10,000 be imposed, pursuant to 740 Ill. Comp. Stat. 92/5(b), for each fraudulent claim that Defendants presented or caused to be presented to an Illinois insurance company;

G. That the Court, pursuant to Cal. Ins. Code § 1871.7(b) and 740 Ill. Comp. Stat. 92/5(b), issue an order preventing the Defendants from transferring, concealing, or dissipating the proceeds of its illegal conduct;

H. That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

I. That the Court issue an order enjoining the Defendants from continuing to engage in the fraudulent conduct alleged herein; and

J. That this Court award such further relief as it deems just and proper.

JURY DEMAND

Relator hereby demands a trial by jury on all claims so triable in this action.

Dated: May 16, 2019

BARON & BUDD, P.C.

By: */s/ W. Scott Simmer*
W. Scott Simmer

Eric Kennedy
WEISMAN, KENNEDY & BERRIS CO., L.P.A.
101 W. Prospect Avenue
Midland Building, Suite 1600
Cleveland, OH 44115
Phone: 216.789.2130
Fax: 216-781-6747

W. Scott Simmer (*pro hac vice* pending)
Noah M. Rich (*pro hac vice* pending)
ssimmer@baronbudd.com
BARON & BUDD, P.C.
The Watergate
600 New Hampshire Ave. NW, 10th Floor
Washington, DC 20037
Telephone: (202) 333-7352
Facsimile: (202) 337-1039

John R. Davis (*pro hac vice* pending)
jdavis@slackdavis.com
SLACK DAVIS SANGER, LLP
2705 Bee Cave Rd., Ste. 220
Austin, TX 78746
Telephone: (512) 795-8686
Facsimile: (512) 795-8787

Attorneys for Relator